UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

CAREFIRST OF MARYLAND, INC., GROUP HOSPITALIZATION AND MEDICAL SERVICES, INC., and CAREFIRST BLUECHOICE, INC., on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

AMGEN, INC., AMGEN MANUFACTURING, LIMITED, and IMMUNEX CORPORATION,

Defendants.

Civil Action No. _____

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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The plaintiffs, CareFirst of Maryland, Inc., Group Hospitalization and Medical Services, Inc., and CareFirst BlueChoice, Inc. (collectively, "CareFirst"), on behalf of themselves and all others similarly situated, allege the following against the defendants, Amgen Inc. and wholly owned subsidiaries Amgen Manufacturing, Limited and Immunex Corporation (collectively, "Amgen"). The plaintiffs' allegations are based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

I. INTRODUCTION

1. The plaintiffs, who provide healthcare benefits to millions of Americans, bring this case against Amgen for unlawfully delaying competition for its blockbuster drug, Enbrel (etanercept). Amgen engaged in a long-running and successful scheme to build and buttress its monopoly power over Enbrel, reaping billions in profits while denying purchasers and patients access to the lower prices they would have paid in a competitive market.

2. The pharmaceutical company Immunex launched etanercept under the brand name Enbrel in 1998. Enbrel is a biologic medicine used to treat a range of disabling inflammatory diseases, including rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis.

3. After biopharmaceutical giant Amgen acquired Immunex and the rights to Enbrel in 2002, Enbrel quickly became Amgen's most lucrative asset. And despite having been launched in the United States more than a quarter-century ago, Enbrel remains a crown jewel of Amgen's $28-billion-a-year portfolio. Enbrel's extraordinarily high prices—which Amgen has increased nearly every single year—are a result of Amgen's unlawful campaign to thwart competition. In total, Amgen and Immunex have amassed more than $86 billion from cumulative worldwide sales of Enbrel.

4. Amgen's staggering Enbrel profits for at least the last five years are attributable to its unlawful campaign to buttress and entrench what was once a legitimate, patent-protected Enbrel monopoly by preventing competition from biosimilar versions of the drug. Like generics, biosimilar drugs have no meaningful differences in safety or effectiveness but are significantly less expensive than their brand-name counterparts. But every drug company that has tried to bring a competing biosimilar version of Enbrel to market has been blocked by Amgen's unlawful actions. If not enjoined, Amgen's illegal monopoly will remain in place until at least 2029, at which point Amgen will have enjoyed *three decades* of market exclusivity—far more than the patent or antitrust laws permit.

5. Amgen first began crafting its anticompetitive scheme in the mid-2000s. Just three years after acquiring the rights to Enbrel, Amgen was raking in massive profits. By mid-2004, annual sales were approaching $2 billion per year, the FDA had approved the drug for multiple indications, and, free of competition, Amgen was able to increase the price of Enbrel annually without any drop in sales. Amgen enjoyed all the economic perks of a monopolist, and its short- and mid-term Enbrel projections showed that it would continue to reap massive profits as a result of its supracompetitive pricing.

6. However, the long-term Enbrel sale projections presented a major problem. The patent portfolio that Amgen had built to protect Enbrel from competition would likely fail to hold back biosimilar versions of etanercept beyond 2015. By then, the Immunex patents that Amgen had acquired would expire, and any additional patents Amgen might be able to obtain were unlikely to keep competing drugs fully off the market.

7. At the same time, Amgen faced another threat: a competing drug company, F. Hoffman-La Roche AG ("Roche"), owned some of the key patents covering Enbrel. While

Roche had granted Amgen a non-exclusive license to those patent rights, nothing prevented Roche from licensing them to other drug companies seeking to develop biosimilar etanercept products to compete with Enbrel (or from developing a competing product itself)—a threat that would likely be realized once Amgen's own Enbrel patents expired.

8. Amgen therefore had a choice: accept that its monopoly over etanercept would come to a natural end (and with it, the massive profits Amgen had been collecting year-over-year) or take steps to extend its monopoly beyond the lawful limits.

9. Amgen chose the latter. Sitting atop a monopoly on the U.S. etanercept market, Amgen sought to maintain, extend, and further entrench its power by buying up exclusive patent rights from Roche that otherwise would have enabled a competitor to enter the market at least by 2019 (and as early as 2016). In mid-2004, Amgen obtained exclusive rights to Roche's patents and patent applications, taking over the prosecution of those pending applications so it could amend them to protect Enbrel and enforce them against any would-be competitors—thereby buying itself decades more monopoly power and pricing.

10. Armed with a reinforced patent portfolio, Amgen weaponized those patents against would-be competitors. Beginning in 2016, Amgen sued every drug company seeking to launch a biosimilar etanercept product to compete with Enbrel. In its lawsuits, Amgen relied on the Roche patents it had unlawfully acquired, suing competitors for allegedly infringing the Roche patents and then utilizing the strength of its overall portfolio to strong-arm competitors into settlement agreements that guaranteed Enbrel would face no competition before 2029. Amgen's goal was clear: block biosimilar competitors, perpetuate supracompetitive pricing, and extend anticompetitive sales of Enbrel for many more years.

11. While the settlement and license agreements have prevented any biosimilar etanercept products from competing with Enbrel and driving down prices, these competitors have stood at the ready for years. Etanercept manufacturers were some of the first drug companies to obtain FDA approval of biosimilar products—deemed safe and identical to Enbrel in all significant ways—securing the necessary regulatory approval to launch their biosimilars by at least 2019, if not earlier. If not enjoined, Amgen will succeed in its efforts to unlawfully delay biosimilar entry in the U.S. for over a decade.

12. Amgen's anticompetitive strategy has worked. Once it controlled the Roche patents, Amgen was able to illegally prolong its U.S. Enbrel monopoly for at least 10 more years—so far. Despite Amgen's chokehold on the U.S. etanercept market, biosimilar etanercept launched in Europe *eight years ago*. Meanwhile, although it launched in the United States more than a quarter-century ago, Enbrel worldwide gross sales exceeded $3.6 billion in 2023 alone.

13. Because of Amgen's unlawful acts, purchasers of etanercept in the United States have overpaid at least $3–4 billion to date and continue to pay supracompetitive prices for the drug. If Amgen's conduct is not enjoined, purchasers' damages will continue to mount for at least five more years until the Roche patents expire.

14. CareFirst, on behalf of a class of purchasers, alleges violation of federal and state antitrust and related laws. Injunctive relief is sought to, among other things, enjoin Amgen's *exclusive* use of the Roche etanercept patents. Monetary relief is sought for overcharges caused by the wrongdoing, and, where appropriate, the damages should be doubled or trebled under law.

II. PARTIES

15. Plaintiff CareFirst of Maryland, Inc. (CFMI) is a not-for-profit corporation organized and existing under the laws of the State of Maryland, with a principal place of business at 1501 South Clinton Street, Baltimore, Maryland 21224.

16. Plaintiff Group Hospitalization and Medical Services, Inc. (GHMSI) is a not-for-profit corporation founded pursuant to an act of Congress, with a principal place of business at 840 First Street, NE, Washington, DC 20065.

17. CFMI and GHMSI both do business as CareFirst BlueCross BlueShield (CareFirst BCBS), and both are independent licensees of the Blue Cross and Blue Shield Association.

18. In fulfillment of its mission to provide affordable and accessible health benefits to its members, including employees of the federal government residing and/or employed in Maryland, the District of Columbia, and Virginia, including Hampton Roads, CareFirst BCBS indirectly purchases Enbrel for members of its private healthcare plans and its Medicare Advantage plans. For Medicare Advantage members that receive Enbrel injections from a physician, these purchases are provided as part of Medicare Part B coverage. For Medicare Advantage members that perform their own Enbrel injections at home (or receive injections from caregivers at home), these purchases are provided as part of Medicare Part D coverage.

19. CareFirst BCBS has purchased Enbrel for its members for several years and anticipates continuing to purchase Enbrel for its members through at least 2029.

20. Plaintiff CareFirst BlueChoice, Inc. (BlueChoice) is a corporation organized and existing under the laws of the District of Columbia, with a principal place of business at 840 First Street, NE, Washington, DC 20065. BlueChoice, an independent licensee of Blue Cross Blue Shield Association, provides health benefit plans for employees of the federal government residing and/or employed in Maryland, the District of Columbia, and Virginia, including Hampton Roads.

21. BlueChoice has purchased Enbrel for its members for several years and anticipates continuing to purchase Enbrel for its members through at least 2029.

22. All the plaintiffs, collectively referred to herein as "CareFirst," are indirect subsidiaries of CareFirst, Inc., a corporation organized and existing under the laws of the State of Maryland. Jointly, these plaintiffs provide or administer health insurance for millions of individuals.

23. CareFirst purchases prescription drugs at third-party pharmacies, like CVS, Walgreens, and Rite Aid, where CareFirst's health plan members have prescriptions filled. CareFirst incurs substantial costs associated with its members' transactions at these third-party pharmacies.

24. Defendant Amgen Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

25. Defendant Amgen Manufacturing, Limited is a corporation existing under the laws of the Territory of Bermuda, with its principal place of business at Road 31 Km 24.6, Juncos, Puerto Rico 00777. Amgen Manufacturing is a wholly owned subsidiary of Amgen Inc.

26. Defendant Immunex Corporation is a corporation organized and existing under the laws of the State of Washington with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. acquired Immunex in July 2002, and Immunex became a wholly owned subsidiary of Amgen Inc.

27. In this complaint, Amgen Inc., Amgen Manufacturing, and Immunex are collectively referred to as "Amgen."

III. JURISDICTION AND VENUE

28. This action alleges violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, and of state antitrust, consumer protection, and related laws. This action seeks declaratory and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and seeks monetary relief

pursuant to state laws. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), § 1332(d)(2) (class action exceeding $5 million), § 1337(a) (antitrust enforcement), and § 1367(a) (supplemental jurisdiction).

29. Venue is proper in this district pursuant to 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because, during the class period, Amgen resided, transacted business, was found, or had agents in this district, and a substantial portion of the alleged activity affecting interstate trade and commerce discussed below has been carried out in this district.

30. This Court has personal jurisdiction over Amgen. Amgen conducts business throughout the United States, including in this district, and has purposefully availed itself of the laws of the United States.

31. During the class period, Amgen manufactured, sold, and shipped Enbrel in a continuous and uninterrupted flow of interstate commerce, which included sales of Enbrel in this district, advertisement of Enbrel in media in this district, monitoring prescriptions of Enbrel by prescribers within this district, and employment of product detailers in this district, who, as agents of Amgen, marketed Enbrel to prescribers in this district.

32. As alleged below, CareFirst purchased Enbrel for its members who are located within this district, including in Norfolk and Virginia Beach.

33. Because of Enbrel's high treatment persistence rate and the chronic nature of the diseases it treats, CareFirst anticipates continuing to purchase Enbrel for members located in this district and this division.

34. Amgen, throughout the United States and including in this district, has transacted business, maintained substantial contracts, or committed overt acts in furtherance of its illegal

scheme. Amgen's unlawful conduct has had a direct, substantial, and reasonably foreseeable effect on interstate commerce, including commerce within this district.

35. Aside from sales of Enbrel, Amgen transacts substantial business in this district, including business related to the promotion and development of Enbrel and to the unlawful scheme alleged here.

36. By reason of the unlawful activities alleged herein, Amgen has substantially affected and continues to substantially affect commerce throughout the United States, causing injury to CareFirst and class members. Amgen, directly and through its agents, has engaged and continues to engage in activities to suppress competition, drive up brand sales, and fix, raise, maintain, and/or stabilize the price of Enbrel in the United States. This conduct has unreasonably restrained trade and adversely affected the market for the direct sale and purchase of etanercept throughout the United States, including in this district, and continues to do so.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The relevant federal regulatory structure encourages competition among pharmaceutical companies.

37. Biologics are large, complex molecules derived from living organisms like human cells, animal cells, and microorganisms (e.g., bacteria or yeast) and often produced through biotechnical or other more recently developed methods. They include a wide range of products, including vaccines, gene therapies, blood components, and recombinant proteins. Unlike traditional small-molecule drugs that are chemically synthesized and have a well-defined structure, biologics are complex mixtures that are not easily identified or characterized.

38. Biologics are licensed under § 351 of the Public Health Service Act (PHSA). To get approval to market a new biologic product, an applicant must submit a biologics license

application (BLA) to the FDA.[1] The FDA may grant the BLA if, among other things, the manufacturer has demonstrated that the biologic and its manufacturing processes and facilities meet standards to assure that the product is safe, pure, and potent.[2]

39. A biosimilar is a drug that is highly similar, but not structurally identical to, a brand-name biologic (referred to as the innovator or reference product). Before 2010, biosimilars were, like small-molecule brand and generic drugs, approved under the Food, Drug and Cosmetic Act (FDCA). But because of the complexity of biologics and the fact that they often require complex, sensitive manufacturing processes, it is not feasible to create an exact duplicate of an existing biologic. Biosimilars therefore could not be approved via the abbreviated pathway for generic small-molecule drugs established by the Hatch-Waxman Act, which requires the sponsor to show the generic has the same active ingredients, strength, dosage form, and route of administration and is bioequivalent to an approved brand-name drug.

40. Recognizing the need for an abbreviated approval process for biosimilars,[3] Congress passed the Biologics Price Competition and Innovation Act (BPCIA) as part of the

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[1] 42 U.S.C. § 262(a).

[2] 42 U.S.C. § 262(a)(2)(C)(i)(I).

[3] In February 2009, the Obama administration proposed establishing a "workable regulatory, scientific, and legal pathway for generic versions of biologic drugs" to "accelerate access to" biosimilars and combat the "high and rising" costs of prescription drugs. Office of Mgmt. & Budget, *A New Era of Responsibility*: *Renewing America's Promise* at 28 (2009), https://www.govinfo.gov/content/pkg/BUDGET-2010-BUD/pdf/BUDGET-2010-BUD.pdf. While debating the yet-enacted BPCIA in June 2009, Senator Sherrod Brown argued that "[p]erhaps nowhere [is the need to bring down costs and increase access] more obvious than the area of biopharmaceuticals or so-called biologics . . . . With costs to biologics ranging anywhere from $10,000 to $200,000 per patient per year, biologic treatments pose a significant financial challenge for patients, for insurance companies, for employers who are paying the bills, and for Federal and State governments that are also paying the bills." 155 Cong. Rec. S6793 (daily ed. June 18, 2009). Representative Frank Pallone similarly stated that "[i]f biologics are the future, then we should do everything we can now to control costs while aiding innovation, just like

Affordable Care Act, signed into law on March 23, 2010. The purpose of the BPCIA was to create a regime for biosimilars, similar to the one created by the Hatch-Waxman Act for generic drugs, in order to promote competition and lower prices in the biologics markets.

41. The BPCIA amended the PHSA to create an abbreviated licensure pathway for biosimilars. Under § 351(k) of the PHSA, a company seeking to market a biosimilar product in the United States must first submit to the FDA an abbreviated biologics license application (aBLA) with information demonstrating, among other things, biosimilarity to the reference (brand) product based on data from analytical studies, animal studies, and clinical studies. The FDA will grant approval if this data shows the product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency."[4]

42. A biosimilar manufacturer may not submit an aBLA until four years after the reference product is first licensed, and an aBLA may not be approved until twelve years after the reference product is first licensed.[5] Put another way, the manufacturer of a new biologic drug enjoys a statutory twelve-year monopoly over its product without biosimilar competition. Thereafter, biosimilars are free to compete—subject to lawful patent restraints.

43. Under certain circumstances, pursuant to the BPCIA, the FDA can also designate a biosimilar as "interchangeable," meaning the biosimilar "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference

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Hatch-Waxman did." *Emerging Health Care Issues: Follow-On Biologic Drug Competition: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 2 (2009).

[4] 42 U.S.C. § 262(i)(2); *see also* 42 U.S.C. § 262(k)(2)(A).

[5] 42 U.S.C. § 262(k)(7).

product."[6] Depending on the relevant state's laws, an interchangeable biosimilar may be substituted for the biologic at the pharmacy without a new prescription in the same way that generics can be. These state laws, referred to as automatic substitution laws, are designed to save purchasers money on their prescription drugs.

44. To obtain an interchangeability designation, a biosimilar applicant must submit to the FDA data sufficient to demonstrate that its product "is biosimilar to the reference product [and] can be expected to produce the same clinical results as the reference product in any given patient . . . ."[7] The first biosimilar approved as interchangeable to the reference product enjoys an exclusivity period. The length of the exclusivity period depends on (a) whether, at the time the FDA granted the biosimilar maker's application for interchangeability, any patent infringement litigation related to that application (i) had already concluded, (ii) was ongoing, or (iii) had not yet begun; and (b) the date on which the interchangeable biosimilar was first commercially marketed.[8]

B. Biosimilar competition lowers drug prices.

45. Biosimilar competition is a relatively recent source of healthcare savings. The FDA approved the first biosimilar in 2015. As of June 2024, the FDA had approved only 56 biosimilars—including two etanercept biosimilars, Erelzi and Eticovo, in August 2016 and April 2019, respectively.[9]

[6] 42 U.S.C. § 262(i)(3).

[7] 42 U.S.C. § 262(k)(4).

[8] 42 U.S.C. § 262(k)(6).

[9] Biosimilar Product Information, FDA, https://www.fda.gov/drugs/biosimilars/biosimilar-product-information (last visited July 1, 2024).

46. While there are some differences in distribution, pharmacy-counter substitution, and prescription writing practices of biosimilar and generic drugs, the same general economic principle applies: biosimilar competition, like generic competition, lowers drug prices and saves healthcare dollars. According to the FDA, as of 2021, biosimilars in the United States "launched with initial list prices 15% to 35% lower than comparative list prices of the reference products."[10] According to the 2023 U.S. Generic and Biosimilar Medicines Savings report, "biosimilars, on average, are priced more than 50 percent lower than the brand biologic[] price at the time of biosimilar launch."[11] And the "[b]rand biologics respond to biosimilar entry by lowering their prices to date, by 25 percent on average."[12]

47. Numerous studies have estimated the amount of savings (determined by estimated price reductions, penetration, and the like) resulting from the introduction of biosimilars. A 2014 Rand review of studies examining individual biosimilars' price impact and market penetration found that in the coming decade, on average, biosimilars would gain a market penetration of 60% and would reduce prices by 35% and would result in about $44 billion in savings over those ten years.[13] The review study also noted that 60% market penetration was a conservative

[10] Press Release, FDA, FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes.

[11] Assoc. for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* at 30 (2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[12] *Id.*

[13] Andrew W. Mulcahy, Zachary Predmore & Soeren Mattke, RAND, *The Cost Savings Potential of Biosimilar Drugs in the United States* at 7 & n.17 (2014), https://www.rand.org/pubs/perspectives/PE127.html.

estimate and that the Congressional Budget Office anticipated a 40% price reduction in the long term.[14]

48. Actual savings far exceeded expectations. A more recent Rand review from 2022, projecting U.S. savings from biosimilar entry from 2021 to 2025, found that total estimated savings from 2014 to 2025 would amount to $102.5 billion, $38.4 billion of which was projected savings from 2021 through 2025 from expanded biosimilar competition.[15]

49. The 2023 *U.S. Generic and Biosimilar Medicines Savings* report found that biosimilars generated $23.6 billion in savings since 2015, including over $9.4 billion in 2022 alone.[16] And a third study estimated that biosimilar entry could result in $100 billion in savings between 2020 and 2024.[17] These results were also confirmed by the 2022 Rand study published in the *American Journal of Managed Car*e and a 2023 IQVIA study. Assuming a higher biosimilar entry probability ($46.5 billion), higher biosimilar volume share ($48.3 billion), lower biosimilar prices ($52.8 billion), and lower prices for reference biologics ($82.4 billion), the study found potential savings could reach $124.2 billion between 2021 and 2025.[18] In 2023, an

[14] *Id.*

[15] Andrew W. Mulcahy & Christine Buttorff, *Projected US Savings from Biosimilars, 2021–2025*, 28 Am. J. Managed Care 329, 331 (2022), https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025.

[16] Assoc. for Accessible Medicines, *The U.S. Generic & Biosimilar Medicines Savings Report* at 27 (2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[17] IQVIA, *Biosimilars in the United States: 2020–2024* at 17 (2020), https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024 ("IQVIA Biosimilars Report").

[18] Mulcahy & Buttorff, *supra* note 15, at 234.

IQVIA study concluded that savings from biosimilars would balloon to $181 billion between 2023 and 2027.[19]

V. FACTS

A. Etanercept is a biologic that reduces the symptoms of inflammatory diseases.

50. Enbrel is a brand-name biologic approved by the FDA for the treatment of rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis. The active ingredient in Enbrel is etanercept. It is sold in single-dose prefilled syringes that patients generally self-administer via weekly injections (typically, one 50-mg injection per week).

51. Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis are autoimmune disorders which result from malfunctions of the body's immune system that cause it to attack its own cells or tissues. These internal attacks can take various forms, including prolonged inflammatory responses that can damage the body's vital organs. As many as 50 million Americans—80% of whom are women—have an autoimmune disease.

52. Rheumatoid arthritis, which affects more than 1.3 million Americans, occurs when the immune system attacks the lining of the joints, leading to chronic inflammation that can cause pain, stiffness, swelling and, over time, bone erosion and joint deformity. It can also cause fatigue, fevers, and loss of appetite and affect the heart, lungs, blood, nerves, eyes, and skin.

53. Plaque psoriasis is a chronic condition in which the immune system causes skin cells to multiply too quickly, causing patches of skin to become scaly and inflamed. Some people

[19] IQVIA, *Biosimilars in the United States: 2023–2027* at 29 (2023), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027.

with psoriasis develop psoriatic arthritis (PsA), which causes pain, swelling, and stiffness of the joints, tendons, and ligaments. Psoriasis also increases the risk of cardiovascular events like heart attack and strokes, mental health problems, certain cancers, Crohn's diseases, diabetes, metabolic syndrome, obesity, osteoporosis, eye inflammation, liver disease, and kidney disease.

54. Ankylosing spondylitis causes inflammation in the joints and ligaments of the spine, resulting in back pain, stiffness, and loss of flexibility. In severe cases, it can cause the vertebrae to fuse, making the spine rigid and inflexible. People with ankylosing spondylitis can suffer from severe, ongoing pain and may also develop inflammatory diseases of the eye, skin, or gut.

55. Juvenile idiopathic arthritis (JIA) includes several chronic disorders in children involving inflammation of the joints, causing pain, swelling, warmth, stiffness, and loss of motion. While the origins of JIA are not understood, it begins with inflammation caused by overactivation of the immune system. JIA can last for only a few months or years but, in some cases, becomes a lifelong disease requiring treatment into adulthood.

56. The immune system is made up of various cells and antibodies that protect the human body from foreign invaders. Antibodies have two main functions: (1) binding to foreign substances called antigens, preventing the antigens from infecting cells or spreading throughout the body, and (2) recruiting[20] other parts of the immune system to attack antigens.

57. One form of antibody is called immunoglobulin G (Ig),[21] which has four subclasses in humans: IgG1, IgG2, IgG3, and IgG4. IgG is protein that consists of two heavy and

[20] Antibodies recruit other immune cells by marking the antigens so that immune cells can then recognize and destroy them.

[21] IgG is the most common antibody in the bloodstream making up about 75% of total antibodies in the human body. In addition to IgG, there are four other types of immunoglobulins: IgA, IgM, IgD, and IgE.

two light amino acid chains, each of which has variable and constant regions. The constant regions interact with other components of the immune system to elicit a response, while the variable regions bind to antigens.

58. Another component of the immune system is called a cytokine. Cytokines are messenger proteins with a wide range of functions, including initiating immune responses, such as regulating inflammation in the body. One of the dozens of cytokines made by the human body is tumor necrosis factor (TNF). TNF is associated with rheumatoid arthritis, PsA, ankylosing spondylitis, and JIA.

59. TNF activates inflammatory pathways by binding to TNF receptors (TNFRs). TNFRs have three regions: intracellular, transmembrane, and extracellular. The extracellular portion can be split off to produce a fragment of TNFR that can bind to TNF. There are two distinct TNFRs that exist naturally on cell surfaces: one with a molecular weight of approximately 55 kilodaltons (p55), and another weighing approximately 75 kilodaltons (p75).

60. Etanercept, a fusion protein produced by combining DNA sequences encoding parts of different proteins into one sequence and introducing that sequence into host cells, consists of the extracellular region of a p75 TNFR combined with an IgG1. It works by making a soluble protein that binds to TNR and blocks its interaction with cell surface TNFRs. By rendering TNF biologically inactive, etanercept reduces inflammatory responses in patients with diseases that cause TNF elevation.

B. In the mid-1980s, researchers at Roche and Immunex raced to develop and patent technologies to treat autoimmune conditions.

1. Roche scientists were the first to sequence the p55 TNFR and create TNFR-Ig fusion proteins, paving the way for new treatments.

61. In the mid-1980s, advances in understanding the role of cytokines in inflammatory diseases, along with the development of new molecular tools enabling scientists to

study cytokine expression and regulation, generated significant interest in the study of TNR and the potential therapeutic applications of inhibiting its ability to bind to TNFRs.

62. A Roche research team led by Dr. Werner Lesslauer made fundamental contributions to the development of TNFR fusion proteins. This Roche team was the first to experimentally prove the existence of two distinct human TNFRs, the p55 and p75, and set out to isolate, purify, sequence, and clone them. In April 1990, the Roche scientists published the amino acid sequences for the p55 TNFR and its encoding DNA. In July 1990, Roche published the same for the p75 TNFR.

63. The Roche scientists were also the first to investigate combining the extracellular regions of TNFRs with portions of immunoglobulins to inhibit inflammatory immune responses and ultimately succeeded in creating fusion proteins using both p55 and p75 TNFRs. While the Roche team's initial fusion protein used IgG3, its experimental work also contemplated the creation of fusion proteins with IgG1 and IgG2.

64. On August 31, 1990, the Roche scientists filed European Patent Application No. 90116707.2 (the "EP '707 Application"), claiming priority[22] to three earlier applications it had filed in Switzerland,[23] which disclosed and taught the concept of fusing the extracellular regions of the p55 and p75 TNFRs with a specific region of a human IgG heavy chain. The patents that would later issue from these applications (shown in Figure 1 below) are referred to as the "Brockhaus Patents."

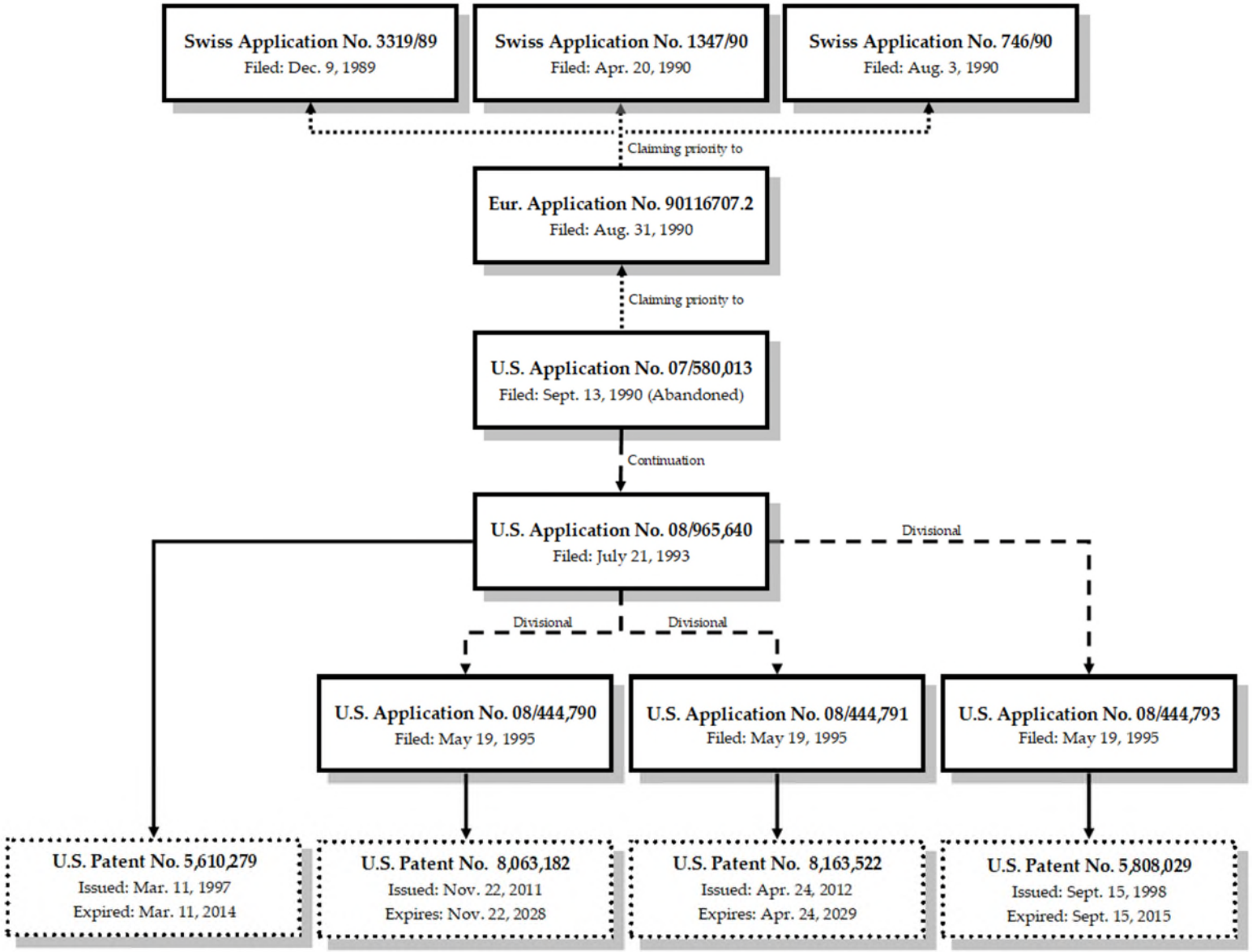
[22] An application that properly claims priority to an earlier-filed patent application receives the filing date of the earlier-filed application, which determines what prior art references can and cannot be asserted against the application during its examination.

[23] Swiss Application Nos. 3319/89 (filed September 12, 1989), 746/90 (filed March 8, 1990), and 1347/90 (filed April 20, 1990).

65. On September 13, 1990, Roche filed U.S. Patent Application No. 07/580,013 (the "'013 Application"), claiming priority to the EP '707 Application.

66. Roche abandoned the '013 Application and, on July 21, 1993, filed U.S. Application No. 08/095,640 (the "'640 Application") as a continuation. The '640 Application was subject to a restriction requirement—because it claimed multiple distinct inventions (related to the p55 and p75 fusion proteins), Roche would be limited to only one of the claimed inventions unless it amended and pursued only one in the application. Roche decided to pursue claims related to the p55 fusion protein in the '640 Application (which later issued as U.S. Patent No. 5,610,279 (the "'279 Patent")). Roche was nonetheless able to pursue the p75 fusion protein claims by filing two divisional applications on May 19, 1995: (1) U.S. Patent Application No. 08/444,790 (the "'790 Application," which would later issue as U.S. Patent No. 8,063,182), claiming the p75 fusion protein, and (2) U.S. Patent Application No. 08/444,791 (the "'791 Application," which would later issue as U.S. Patent No. 8,163,192), claiming a method of producing the p55 fusion protein.

Figure 1. Brockhaus Patent Tree



2. Immunex scientists were the first to sequence the p75 TNFR and create etanercept.

67. Meanwhile, Immunex was independently researching TNFRs and TNFR fusion proteins, focusing on the p75 TNFR. In May 1990—two months before Roche—Immunex scientists published the amino acid sequence for the p75 and reported that they had isolated a cDNA clone of its receptor.

68. In late 1990, Immunex successfully combined the extracellular portion of a p75 receptor with the hinge-CH2-CH3 portion of a human IgG1—i.e. the fusion protein etanercept, the active ingredient in Enbrel.

69. Immunex obtained a series of patents directed to etanercept and methods of using etanercept stemming from various continuations-in-part of U.S. Patent Application No. 07/403/241, filed September 5, 1989 (abandoned).

70. On May 10, 1990, Immunex filed U.S. Patent Application No. 07/523,635, which issued as U.S. Patent No. 5,395,760 (the "'760 Patent") on March 7, 1995. Entitled "DNA Encoding Tumor Necrosis Factor-α and -β Receptors," the '760 Patent claims specified isolated DNA sequences that encode soluble human TNFRs, including the p75. It expired on March 7, 2012.

71. On February 8, 1995, Immunex filed U.S. Patent Application No. 08/383,229, which issued as U.S. Patent No. 5,605,690 (the "'690 Patent") on February 25, 1997. The '690 Patent, entitled "Methods of Lowering Active TNF-α Levels in Mammals Using Tumor Necrosis Factor Receptor," claims methods of treating TNF-dependent inflammatory diseases in mammals by administering a TNF antagonist such as a soluble TNFR. It expired on February 25, 2014.

72. On January 27, 1998, Immunex filed U.S. Patent Application No. 08/346,555, which issued as U.S. Patent No. 5,712,155 (the "'155 Patent") on November 29, 1994. Entitled

"DNA Encoding Tumor Necrosis Factor-α and -β Receptors," the '155 Patent claims specified isolated DNA sequences that encode soluble human TNFRs, including the p75. It expired on March 7, 2012.

C. Immunex launches Enbrel and obtains a non-exclusive license to the Brockhaus Patent Rights.

1. The FDA approves Enbrel as the first TNF inhibitor monotherapy to treat rheumatoid arthritis.

73. On November 2, 1998, the FDA approved Enbrel for the treatment of moderate to severe rheumatoid arthritis in patients with an inadequate response to one or more disease-modifying, antirheumatic drugs. Immunex launched Enbrel in the United States on November 6, 1998.

74. Enbrel was hailed as a breakthrough in rheumatoid arthritis treatment. Before its launch, the gold standard for rheumatoid arthritis treatment was low-dose methotrexate, which had favorable responses in only 30% of patients and often could not be tolerated for extended periods. More recent rheumatoid arthritis therapies like Remicade and Anakinra were either used in combination with methotrexate or targeted a later disease stage. Enbrel, therefore, "st[ood] alone as an adult and juvenile rheumatoid arthritis treatment that can be used with or without" methotrexate, including in early stages of the disease, and had "no real competitor."[24]

2. Immunex seeks and gets a non-exclusive license from Roche for the Brockhaus Patent Rights.

75. On November 6, 1998, Immunex launched Enbrel for the treatment of early and moderate to severely active rheumatoid arthritis. At the time, Immunex neither owned nor had a

[24] Debra Robertson, *Immunex Takes Premature Step to Guarantee Enbrel Market Share*, 19 Nature Biotech. 108, 109 (Feb. 2001).

license to Roche's EP '707 Application teaching the fusion of extracellular regions of p75 TNFRs with a specific region of a human IgG heavy chain.

76. Because the EP '707 Application gave Roche priority to the p75-IgG1 fusion technology used to create Enbrel, Immunex sought and obtained from Roche a license to the "Brockhaus Patent Rights," i.e., all "patents and patent applications that issue from or that claim priority of Swiss Patent Application Nos. 3319/89, 746/90, and/or 1347/90, including, but not limited to, European Application No. 90116707.2 and U.S. Patent Application No. 07/580,013."[25]

77. Roche and Immunex executed a license agreement (the "1998 License Agreement") on September 15, 1999, with an effective date of November 6, 1998 (the date of Enbrel's launch). Under the 1998 License Agreement, Roche granted Immunex a co-exclusive license (the "1998 License") under the Brockhaus Patent Rights to make, use, sell, and import etanercept worldwide. "Co-exclusive" meant that Immunex and Roche each had the right to commercialize etanercept worldwide. Roche also had the right to grant co-exclusive rights in each country to (a) one licensee in lieu of or in collaboration with Roche, (b) a single third-party to distribute etanercept within that country in lieu of Roche and its licensee, and (c) a contract manufacturer to manufacture etanercept for use, sale, importation, and/or distribution by Roche and its licensee.[26] In other words, Roche in 1998 maintained the right to manufacture etanercept itself or to allow a non-Immunex third-party to do so.

78. The 1998 License also expressly provided that Roche would retain ownership of the Brockhaus Patents and was responsible at its own discretion for their prosecution and

[25] License Agreement for Etanercept Among Immunex Corp., Hoffman-La Roche Inc., and F. Hoffman-La Roche Ltd. § 1.2 (Sept. 15. 1999) (attached as Ex. 1).

[26] *Id.* § 2.1.

maintenance.[27] Roche also retained the sole right to address infringement of the Brockhaus Patents, including initiating suit, but Immunex agreed to provide reasonable assistance to Roche in taking any such steps and had the right to join any infringement litigation initiated by Roche and to obtain any damages awarded, including lost profits.[28] In other words, Roche in 1998 maintained all core patent rights—the right to prosecute, maintain, and enforce the Brockhaus Patents.

79. In exchange for the non-exclusive license grant, Immunex agreed to pay royalties of 4% of its net sales of etanercept products.[29] Roche also received an option to obtain a worldwide, nonexclusive license from Immunex to certain of its patent rights relating to p55 TNFR fusion proteins, subject to certain conditions.[30]

3. Enbrel is a phenomenal commercial success for Immunex, with $762 million in annual sales by 2001.

80. Enbrel was an immediate blockbuster, earning Immunex $13 million in U.S. sales in its first few *weeks* on the market. In its 1998 annual report, Immunex touted Enbrel's launch as a "key milestone event" and predicted that Enbrel would "drive a revenue 'step change' for Immunex" that would "provide substantial cash flow and fuel the company's growth."[31]

81. Seeking to expand the Enbrel market, Immunex sought and, on May 27, 1999, received, FDA approval of Enbrel for the treatment for polyarticular JIA, making it the first FDA-approved therapy for this indication. Immunex also announced in 1999 that it was

[27] *Id.* §§ 3.1, 3.4.

[28] *Id.* § 3.5.

[29] *Id.* § 5.2.

[30] *Id.* § 2.2.

[31] Immunex Corp., *Annual Report* at 11, 13 (1998), https://digitalcollections.lib.washington.edu/digital/collection/reports/id/24178.

conducting pilot studies and clinical trials to investigate the use of Enbrel for additional indications and partnered with American Home Products Corporation to expand manufacturing capacity. By year end, Enbrel had become an "unprecedented commercial success for Immunex, with $367 million in U.S. sales."[32]

82. In June 2000, the FDA approved an expanded indication for Enbrel, adding reduction of the signs and symptoms and delay of the progression of structural damage in patients with moderately to severely active rheumatoid arthritis. It also eliminated the need for patients to demonstrate an insufficient response to one or more other rheumatic drugs before starting Enbrel treatment—allowing more patients to access Enbrel sooner.

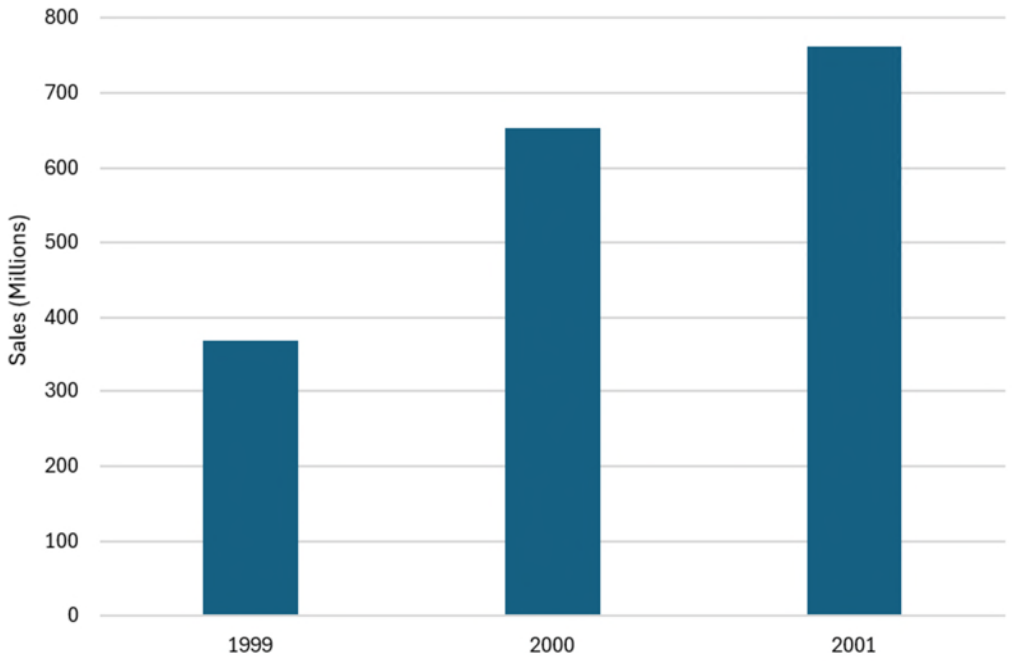
83. Immunex continued "quarter for quarter" to "set new records for sales of Enbrel."[33] By November 2000, there were more than 1,000 patients on a waiting list for the drug; total sales by year end exceeded $650 million. Sales in 2001 increased 17% to $762 million, cementing Enbrel's launch as the most successful ever for a biologic product. As Immunex put it, as a "targeted, potent intervention for inflammation, Enbrel has changed the practice of rheumatology."[34]

[32] Immunex Corp., *Annual Report* at 23–24 (1999), https://digitalcollections.lib.washington.edu/digital/collection/reports/id/24288.

[33] Immunex Corp., *Annual Report* at 1 (2002), https://www.sec.gov/Archives/edgar/vprr/0202/02029646.pdf.

[34] *Id.*

Figure 2. Immunex's U.S. Sales of Enbrel, 1999-2001



84. Immunex also steadily increased the price of Enbrel. When Immunex launched Enbrel in 1998, it set the WAC price at $220 per 50-mg dose ($886 per month). By 2002, Immunex was charging $249 per 50-mg dose ($996 per month).

D. Biotech giant Amgen acquires Immunex and adds Enbrel to its waning portfolio.

85. In December 2001, Amgen Inc., already the largest biotechnology company in the world, announced that it was buying Immunex for $16 billion in cash and stock—the highest sum *ever paid* for a biotech acquisition.

86. Enbrel was the key driver of the deal for Amgen, which had not launched a significant new drug in a decade. Sales of its aging blockbusters Epogen (an anemia treatment) and Neopogen (used to prevent infections in cancer patients undergoing chemotherapy)—once $1-billion-a-year sellers—were floundering. And ten years of substantial investment in inflammation research had garnered few returns. The FDA had approved Amgen's interleukin-1 inhibitor, Kineret (anakinra), for the treatment of moderate to severe rheumatoid arthritis in

November 2001, but sales were projected to be (and were) lackluster. Amgen's second-generation TNR inhibitor, pegsunercept, was only in Phase II development. Yet Amgen's new CEO, Kevin Sharer, who took the helm in 2000, had promised investors at least 20% annual growth in sales and earnings per share and revenues of $8–9 billion by 2005.

87. Enbrel was the solution to Amgen's problems. Amgen executives boasted to investors that Enbrel had the potential to generate more than $3 billion in annual sales by 2005, and Amgen was "enthusiastic about the long-term potential of Enbrel," which it predicted would reach $3 billion by 2005.[35]

1. The FTC requires Amgen and Immunex to license certain TNFR patents to prevent an unlawful monopoly in the TNR inhibitor market.

88. Amgen's acquisition of Immunex, and the impact it would have on the market of drugs used to treat immunological conditions, drew immediate antitrust concerns from government agencies and industry watchdogs.

89. The acquisition was subject to review by the Federal Trade Commission (FTC). The FTC's Bureau of Competition is empowered to prevent "acquisitions that are likely to reduce competition and lead to higher prices, lower quality goods or services, or less innovation."[36] When the Bureau becomes aware of a merger, "bureau lawyers, along with economists from the FTC's Bureau of Economics, investigate market dynamics" to determine if

[35] Andrew Pollack, *Amgen Reports Its Takeover of Immunex*, N.Y. Times, July 17, 2002, https://www.nytimes.com/2002/07/17/business/amgen-reports-its-takeover-of-immunex.html#:~:text="Some%20of%20the%20things%20we,million%20in%20sales%20last%20year.

[36] FTC, *Merger Review*, https://www.ftc.gov/enforcement/merger-review (last visited July 3, 2024).

the merger or acquisition will harm consumers.[37] When deemed necessary, the FTC may take steps before approving the merger or acquisition to protect consumers.

90. After reviewing the proposed acquisition, the FTC issued a complaint against Amgen and Immunex stating that the "effects of the Merger, if consummated, may be to lessen competition and to tend to create a monopoly" in violation of federal antitrust law by, *inter alia*, "reducing innovation" and "eliminating potential competition in" the TNF inhibitor market.[38] The complaint noted that Amgen and Immunex were the only two firms in the United States marketing or developing soluble TNF receptor products and two of only five firms developing any type of TNF inhibitors to treat rheumatoid arthritis and other inflammatory diseases.[39] Because of the significant difficulty, cost, and time required to develop TNF inhibitors, the FTC concluded that the consolidation of Amgen's and Immunex's "substantial proprietary rights" in this market could "create large and potentially insurmountable barriers to entry."[40]

91. Amgen and Immunex settled the FTC's antitrust charges by entering a consent order requiring them, *inter alia*, to license certain patents to Serono—a Swiss pharmaceutical company that was "developing a soluble TNF receptor, Onercept, for use in Europe, but [that did] not possess the patent rights necessary to market the product in the United States"[41]—to

[37] *Id.*

[38] Compl. ¶ 25, *In re Amgen Inc. & Immunex Corp.*, Docket No. C-4053 (F.T.C. July 12, 2002).

[39] *Id.* ¶ 20.

[40] *Id.* ¶¶ 22–24.

[41] *Id.* ¶ 20.

ensure the continued development of TNF inhibitors for sale in the United States and "to remedy the lessening of competition" in that market that would result from the acquisition.[42]

92. The FTC announced on July 12, 2002, that it would allow the acquisition to proceed under the terms of the consent agreement. The acquisition was completed on July 16, 2002, giving Amgen all rights to Enbrel in the United States and Canada.

2. Amgen reaps the rewards of its acquisition as Enbrel becomes one of the most profitable drugs in the world.

93. Once in control of Enbrel, Amgen immediately set out to maximize its return—and make good on its CEO's promises to investors—by increasing Enbrel sales, including by obtaining FDA approval to use Enbrel to treat new immunological conditions and raising Enbrel prices.

94. Amgen's returns were almost immediate. By December 2002, it had recorded $362.1 million in Enbrel sales; combined with Immunex's sales for the first half of the year, total 2002 sales of Enbrel exceeded $770 million. With an estimated 80,000 people taking Enbrel, supply constraints began impacting sales. To keep up with demand, Amgen immediately built a new Enbrel manufacturing facility in Rhode Island.

95. By the time Amgen's acquisition of Immunex was complete, the FDA had approved Enbrel for the treatment of psoriatic arthritis (PsA). At the time, Enbrel was the only FDA-approved treatment for PsA. But even while touting that Enbrel had "the broadest range of indications of any biologic therapy in rheumatic diseases," Amgen set out to obtain even more

[42] Decision & Order at 19, *In re Amgen Inc. & Immunex Corp.*, Docket No. C-4056 (F.T.C. Sept. 3, 2002). Serono's TNF inhibitor, Onercept, was never commercialized.

indications to further bolster sales of the blockbuster.[43] In 2003 and 2004, Amgen succeeded in getting FDA approval for the use of Enbrel to reduce signs and symptoms of ankylosing spondylitis, to treat moderate to severe plaque psoriasis, and to induce a major clinical response (i.e., high level of disease control) in active rheumatoid arthritis. Amgen also introduced new dosing regimens and formulations and got approvals for new age groups.

96. With the expanded indications ushering in new patients in the rheumatology and dermatology marketplaces, Enbrel sales skyrocketed to $1.25 billion in 2003—a 175% increase from the prior year. The 2004 sales increased another 46% to $1.83 billion.

97. As Amgen was expanding Enbrel's indication list, it was also raising its price. Every single year post acquisition, Amgen was able to increase what it charged purchasers, including CareFirst, for Enbrel—all without losing sales to other therapeutic alternatives. These high prices set Amgen and Immunex up to enjoy high profit margins from Enbrel sales.

98. From Enbrel's launch in November 1998 through 2004, Immunex and later Amgen reaped monumental benefits from their monopoly in the U.S. etanercept market, enjoying high profit margins generated by supracompetitive pricing and annual price increases. With future sales of Enbrel projected to exceed $3 billion per year, protecting its golden-goose blockbuster became a crucial priority for Amgen.

99. Amgen went to work to protect its Enbrel monopoly with a thicket of patents, filing dozens of applications for patents claiming Enbrel manufacturing processes, formulations,

[43] Press Release, Amgen, *Amgen Submits Data to FDA Supporting Once-Weekly Dosing of Enbrel* (Dec. 23, 2002), https://www.amgen.com/newsroom/press-releases/2002/12/amgen-submits-data-to-fda-supporting-once-weekly-dosing-of-enbrel.

methods of use, and administration devices.[44] But Amgen knew none of these patents were likely to prevent competing biosimilars from launching after the expiration of Amgen's key Enbrel patents in 2012 (indeed, as explained below, all of these patents were ultimately abandoned in later patent litigation). So, Amgen turned to another strategy: buttressing and entrenching its monopoly by blocking access to patents competitors could use to launch biosimilar etanercept products that would compete with Enbrel.

E. With patent expiration and biosimilar competition on the horizon, Amgen buys out Roche's remaining rights to the Brockhaus Patents.

100. While Amgen had thus far benefited handsomely from its acquisition of Immunex, and thus Enbrel, it saw a cliff ahead. Absent action, Enbrel could face competition from a competing biosimilar etanercept drug launched either directly by Roche or a competing company that obtained rights to Roche's patents—just as Immunex had.

101. Amgen attempted to shore up its defenses to this threat by foreclosing Roche's ability to permit competition. In June 2004, Amgen bought out all of Roche's license rights that Roche had retained for itself in the original 1998 License—i.e., the Brockhaus Patent Rights. The transaction made Amgen the exclusive licensee of the Brockhaus Patents, gave it the ability to further prosecute (and amend) pending patent applications to ensure maximum protection for Enbrel, and enabled it to enforce the Brockhaus Patents and exclude competitors from the etanercept market.

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[44] *See* Jonathan Gardner, *A Three-Decade Monopoly: How Amgen Built a Patent Thicket Around its Top-Selling Drug*, BioPharma Dive (Nov. 1, 2021), https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/; Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 Chi.-Kent J. Intell. Prop. 93 (2020). A 2018 report found that 72% of the at least 57 applications for patents on Enbrel were filed after the product was approved and launched. *See* I-Mak, *Overpatented, Overpriced Special Edition: Enbrel*, https://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf.

102. On June 7, 2004, Amgen and Roche (through Hoffman-La Roche Inc. and F. Hoffman-La Roche Ltd.) signed an "Accord and Satisfaction" (the "2004 Exclusive License") concerning the same patent family (the Brockhaus Patents) that were the subject of the 1998 License.[45]

103. The stated purpose of the agreement was "to eliminate the continuing obligations to pay royalties to Roche" pursuant to the 1998 License.[46] Under the 2004 Exclusive License, Roche agreed to waive future royalty payments, and Amgen agreed to make lump sum payments to Roche totaling $150 million.[47]

104. But the 2004 Exclusive License was far more than an agreement to eliminate the headaches of having to pay royalties calculated over time. The agreement also effectuated a significant change in the license rights of Roche's Brockhaus Patents for Amgen and, in doing so, significantly altered the competitive landscape for etanercept.

105. Under the 2004 Exclusive License, Roche granted Amgen a paid-up, irrevocable, exclusive license, with the sole right to grant sublicenses, to the Brockhaus Patents in North America for the commercialization of etanercept.[48] The only reservation of license rights to

[45] *See* Accord & Satisfaction Among Hoffmann-La Roche Inc., F. Hoffman-La Roche Ltd., Wyeth, AHP Manufacturing B.V., Amgen Inc. & Immunex Corp. (June 7, 2004) (attached as Ex. 2). Wyeth, a Philadelphia-based pharmaceutical company acquired by Pfizer in 2009, and its wholly owned subsidiary AHP Manufacturing were Amgen's marketing partners for Enbrel. The agreement granted Wyeth the "exclusive right to distribute products comprising Etanercept outside North America" and the right to "co-promote products comprising Etanercept within North America." *Id.* at 1. Further, the agreement assigned to Wyeth "(a) all right, title and interest in and to all Ex-North America Brockhaus Patents; and (b) the right to sue and recover for any acts of infringement of any Ex-North America Brockhaus Patents." *Id*. at 3.

[46] *Id.* at 1.

[47] *Id.* at 7.

[48] *Id.* at 4 (Article 3.1).

Roche was for internal, non-clinical research.[49] With respect to patent prosecution, Amgen purchased the right to prosecute patent applications in the U.S. patent family.[50]

106. Thus, as of 2004, Amgen controlled the prosecution of the Brockhaus Patents, including pending applications. The agreement granted Amgen the first right to sue over suspected infringement of the licensed patents at its sole expense and under its sole control—i.e., Amgen had the right to sue other drug companies whose products (like biosimilar etanercept) Amgen believed infringed the patents.[51] Amgen would also keep any award of damages or lost profits resulting from such an infringement suit. Roche is obligated to cooperate in these patent suits, including by participating as a party to the extent required by the court or by providing evidence and testimony in connection with any proceeding affecting the validity of the patents-in-suit.[52] Amgen also has the right to convert its exclusive license to an assignment upon request and upon payment of a relatively trivial sum of $50,000. (If "requested . . . Roche shall execute an assignment of" the patents).[53]

107. As part of the 2004 agreement, Roche retains the secondary right, but not obligation, to sue if Amgen fails to rectify infringement or initiate an action for patent infringement within 180 days after written notification by Roche.[54] The agreement further provides that, once Roche's secondary right to sue is triggered, Roche may, at its sole expense

[49] *Id.* (Article 3.2).

[50] *Id.* at 5 (Article 3.3).

[51] *Id.* (Article 3.5).

[52] *Id.* (Article 3.4).

[53] *Id.* (Article 3.3).

[54] *Id.* at 6 (Article 3.6).

and under its sole control and direction, initiate suit and may retain the entirety of any award of damages or lost profits as a result of such suit.[55]

108. The description of the 2004 Exclusive License as an "Accord & Satisfaction" is, and appears intended by Amgen to be, misleading. In an accord and satisfaction, parties simply settle a previous unliquidated debt. Roche and Amgen could have accomplished that goal by simply agreeing to a lump sum payment in exchange for future royalties and do so without a fundamental change in the nature of the underlying license rights. But Roche and Amgen did not stop there.

109. Instead, the intended and effectuated goal was for Amgen—then a monopolist in the U.S. market for etanercept—to extend and further entrench its monopoly position by foreclosing competition in the United States by Roche or any assignee of Roche to the Brockhaus Patents. Through the 2004 Exclusive License, Amgen bought up Roche's U.S. retained rights to a co-exclusive launch of etanercept products and to commercialize any p75 fusion protein.

110. The 2004 Exclusive License was also falsely labeled because, although it moved functional control of the Brockhaus Patent rights in the U.S. to Amgen, it was structured to leave ostensible back-up rights to Roche. This would later enable Amgen to argue, in any future proceedings, that Amgen did not "own" the Brockhaus Patent rights, and thus the patents that Amgen already did own were not in common ownership with the owner of the Brockhaus Patents (as one observer put it, the agreement "went right up to the line of ownership without

[55] *Id.* (Article 3.6).

actually crossing it"[56]). By doing so, Amgen could seek to extend Enbrel's patent protection by layering on the later-expiring Brockhaus Patents without running afoul of the legal doctrine of double-patenting.[57]

111. The purpose and effect of Amgen's acquisition of the 2004 Exclusive License was wholly anticompetitive. Amgen already had significant rights to market exclusivity under the BPCIA and its existing patents. It sought to prolong that market exclusivity—and entrench its monopoly—by acquiring patents covering a substantial share of the etanercept market, a maneuver prohibited by antitrust laws.

112. *First*, Amgen had its own patents that it had acquired over the years and used to launch Enbrel and protect its sales.[58]

113. *Second*, to the extent that Amgen needed a license from Roche to the Brockhaus Patents, Immunex had already acquired those license rights (effective the date of Enbrel's launch) through the 1998 License granted to Immunex, and that license provided co-exclusive rights. Amgen needed nothing further from Roche to be able to commercialize Enbrel without fear of running afoul of Roche's technology.

114. *Third*, Amgen was enjoying exclusivity under § 351(k)(7) of the PHSA for etanercept that would prohibit the submission, or approval, of any § 351(k) application for a

[56] Doug Robinson, Dickey & Pierce, P.L.C., *End of The Enbrel Battle: How Amgen Beat Sandoz* (Sept. 8, 2020), https://www.biosimilardevelopment.com/doc/end-of-the-enbrel-battle-how-amgen-beat-sandoz-0001.

[57] The double-patenting doctrine, put simply, prevents the same inventor from obtaining additional years of patent protection by patenting the same thing, or an obvious variant thereof, twice.

[58] *See* U.S. Patent No. 5,606,690; U.S. Patent No. 5,395,760; U.S. Patent No. 5,712,155; U.S. Patent No. 11,491,223; U.S. Patent No. 10,307,483; U.S. Patent No. 8,119,604.

proposed biosimilar (or interchangeable) to Enbrel (etanercept) that would not expire until November 2, 2010.[59]

115. Nor was elimination of Roche's co-exclusive rights necessary for the successful development of Enbrel. Immunex (and later Amgen) had already succeeded in reaching blockbuster sales for years. Despite the retained Roche license rights, Immunex and Amgen had made investments in, and gained a monopoly position in, the U.S. market for etanercept.

116. In sum, Amgen's acquisition of an exclusive license to the Brockhaus Patents was intended do, and did in fact, further maintain, extend, and entrench Amgen's existing etanercept monopoly; the acquisition was anticompetitive with no procompetitive benefits.

F. Amgen rewrites Roche's '790 and '791 Applications to cover etanercept and relentlessly prosecutes them to extend its Enbrel monopoly to 2029.

117. As a part of the 2004 Exclusive License, Amgen obtained all rights to control the prosecution of Roche's '790 and '791 Applications—patent applications that had been pending for nearly 10 years. At the time Amgen took over control of these patent applications, *they did not cover etanercept*, instead targeting a different fusion protein altogether.

118. But having secured the rights under the 2004 Exclusive License to take over and steer ongoing patent prosecutions, Amgen immediately set out to make sure that the pending Brockhaus Patents would buttress and protect its Enbrel monopoly. Amgen notified the PTO that Amgen lawyers would be acting as Roche's representatives in the patent prosecutions in October 2004.

[59] Amgen's BLA No. 103795 for Enbrel was first licensed by the FDA under § 351(a) of the PHSA on November 2, 1998, and additional supplements for changes and updates to the approved labeling were approved after this date. The dates that are four and 12 years after the date of first licensure of Enbrel are November 2, 2002, and November 2, 2010, respectively. A licensure of a supplement does not trigger a separate period of exclusivity.

119. Once in control of the ’790 and ’791 Applications, Amgen substantially rewrote them to include claims directed to the p75-IgG1 fusion protein—and thus reshaped them to cover Enbrel. Amgen would prosecute the applications relentlessly for nearly a decade.

120. On December 13, 2004, Amgen filed its first response to the PTO in the prosecution of the ’791 Application. Its first step was to cancel all pending claims (the claims drafted by Roche), add 29 new claims, and modify the specification. Amgen did so to shift the application away from the p55 fusion protein and onto the p75 fusion protein—thus covering etanercept. The examiner entered a final rejection of the patent application on March 12, 2007.

121. Amgen did not give up. In May 2007, it filed a petition for review. On August 22, 2007, the PTO reversed course and withdrew the final rejection. The examiner issued two more non-final rejections, another restriction requirement, and, on June 24, 2011, another final rejection. Amgen countered the examiner’s reasons for rejection on November 23, 2011, and, on December 22, 2011, filed for an appeal. The gambit paid off. The examiner issued a notice of allowance less than two months later, on February 15, 2012. The ’522 Patent issued on April 24, 2012, and will not expire until April 24, 2029.

122. On January 18, 2005, Amgen filed its first response in the ’790 prosecution. In a July 2004 office action entered while Roche controlled the prosecution, the examiner had rejected the claims for non-statutory subject matter (proteins found in nature) and anticipation (the claims were anticipated by prior art—and thus not novel). In its 2005 response, Amgen cancelled, amended, and added claims—again to adjust the applications so that they applied to etanercept. In 2006, Amgen further modified the claims and the specification. The examiner issued two more non-final rejections, followed by a final rejection on February 23, 2007.

123. Amgen did not stand down. It filed its response in August 2007 and requested an oral hearing. On February 28, 2008, Amgen filed an appeal, with its initial briefing alone comprising more than 500 pages. The patent board issued a final decision on November 22, 2010, reversing the examiner. The examiner issued one more non-final rejection in March 2011. Then, on August 31, 2011, the examiner issued a notice of allowance for the '790 application. On November 22, 2011, the PTO issued the U.S. Patent No. 8,063,182 (the "'182 Patent"), which will not expire until November 22, 2028.

124. The amount of time, effort, and expense that Amgen poured into these two applications underscores the importance it placed on the Brockhaus Patents—and its Enbrel monopoly.

125. The timing and targeting of the Brockhaus Patent prosecutions were no coincidence. The '790 and '791 Applications had been filed on May 19, 1995, a few weeks before a critical statute—the Uruguay Round Agreements of the General Agreement on Tariffs and Trade ("GATT")—took effect.[60] GATT impacted how long patent exclusivity terms would run and how they were calculated. As a result of the GATT amendment, patents that issue from applications filed after June 8, 1995 receive a 20-year term from their effective filing date.

[60] Before June 1995, 35 U.S.C. § 154 provided that the term of a utility or plant patent ended seventeen years from the date of patent grant. To comply with Article 33 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement resulting from GATT, the United States was required to establish a minimum term for patent protection ending no earlier than twenty years from the date the application was filed. Thus, the Uruguay Round Agreements Act amended 35 U.S.C. § 154 in June of 1995 to change the term of utility and plant patents from ending 17 years from the date of patent grant to ending 20 years from the filing date of the application (or 20 years from the earliest filing date claimed under 35 U.S.C. §§ 120, 121, or 365(c)). With this change, 35 U.S.C. § 154 was also amended to provide for patent term extension in the event that issuance of the application as a patent was delayed due to secrecy order, interference or successful appellate review, subject to a five-year cap on any patent term extension under 35 U.S.C. § 154(b).

Patents claiming priority to applications filed before June 8, 1995, however, are entitled to a term that is the greater of 20 years from the filing date of the application *or* 17 years from the date of patent issuance.

126. The late issuance of the Roche etanercept patents (in 2011 and 2012) from applications that had been filed pre-GATT (in 1995) was an incredible boon for Amgen. By the time the patents issued, Enbrel had already been on the U.S. marketplace since 1998, about 13 years. Sales were in the billions of dollars every year. With the pre-GATT filing date permitting an additional 17 years of patent protection, use of these patents would mean Amgen could protect sales of Enbrel and avoid competition from any biosimilar versions for *more than 30 years*.

127. Soon after '182 Patent issued, analysts at Sanford C. Bernstein estimated that *this one* patent alone added $6 per share to Amgen's stock price.[61] With approximately 870 million outstanding shares, this single patent issuance potentially added about $5 billion to Amgen's value.

G. Amgen uses the '182 and '522 Patents to block would-be competitors from launching less expensive biosimilar versions.

128. Since Amgen secured the issuance of the '182 and '522 Patents from Roche's '790 and '791 Applications, it has used them to block biosimilar entrants into the U.S. market for etanercept—the final step in unlawfully entrenching and expanding its monopoly.

[61] *See* Staff of H. Comm. on Oversight and Reform, *Drug Pricing Investigation: Amgen—Enbrel and Sensipar* at 24 (Oct. 2020), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Amgen%20Staff%20Report0%2010-1-20.pdf; *see also New Patent Could Be Worth $6 a Share to Amgen*, Forbes, Nov. 28, 2011, www.forbes.com/sites/matthewherper/2011/11/28/new-patent-could-be-worth-6-a-share-to-amgen/#4be44a7a46e1.

1. Amgen successfully sues Sandoz for infringement of the ’182 and ’522 Patents, preventing the launch of its Enbrel biosimilar.

129. Sandoz, a major pharmaceutical manufacturer, became the first potential Enbrel competitor with its Erelzi drug.

130. On September 29, 2015, the FDA accepted Sandoz’s aBLA seeking authorization from the FDA to market Erelzi, a biosimilar version of Enbrel (etanercept).

131. On February 26, 2016, Immunex and Amgen Manufacturing (the two subsidiaries of Amgen), along with Roche, filed a lawsuit against Sandoz (the “*Sandoz* case”). Amgen asserted infringement of the two Roche Patents (the ’182 and ’522 Patents) as well as three of its own patents, 7,915,225 (“the ’225 Patent”), 8,119,605 (“the ’605 Patent”), and 8,722,631 (“the ’631 Patent”) (collectively, the “Psoriasis Patents”). Amgen sought an injunction to prohibit Sandoz from commercializing its biosimilar etanercept prior to the expiry of all the patents.

132. Over the course of the litigation, Amgen narrowed its infringement claims against Sandoz to the ’182 and ’522 Patents, dropping its claims over the Psoriasis Patents and relying exclusively on the Roche Patents to deny its competitor access to the etanercept market.

133. On August 11, 2016, and subject to the terms of a confidential stipulation, the *Sandoz* court entered a preliminary injunction prohibiting Sandoz from commercializing Sandoz’s etanercept product.

134. On August 30, 2016, the FDA approved Erelzi. Given the injunction, however, Sandoz could not launch its biosimilar.

135. On September 10, 2018, the *Sandoz* court entered an order which stated that commercialization of Sandoz’s biosimilar etanercept product would infringe the two Roche Patents (the ’182 and ’522 Patents).

136. On August 9, 2019, and after a bench trial, the *Sandoz* court issued a decision upholding the validity of the ’182 and ’522 Patents.

137. On July 1, 2020, the Federal Circuit affirmed the district court judgment upholding the validity of the ’182 and ’522 Patents.

138. On May 17, 2021, Sandoz’s petition for *certiorari* with the U.S. Supreme Court was denied.

139. Amgen was therefore able to keep Sandoz off the market based entirely on the Roche Patents.

2. Amgen sues Samsung Bioepis for infringement of the ’182 and ’522 Patents and blocks the launch of its Enbrel biosimilar.

140. The next potential competitor was Samsung Bioepis Co., Ltd. (“Bioepis”).

141. On April 25, 2019, the FDA approved Bioepis’s aBLA for its etanercept product Eticovo (etanercept-ykro), another biosimilar to Enbrel.

142. On April 30, 2019, Amgen sued Bioepis (the “*Bioepis* case”), alleging infringement of the Roche Patents (the ’182 Patent and the ’522 Patent) and the same three Psoriasis Patents (the ’225, ’605, and ’631 Patents) that had been asserted against Sandoz. Amgen sought an injunction to prohibit Bioepis from commercializing its biosimilar etanercept prior to the expiry of the patents.

143. On December 23, 2019, Amgen amended its complaint against Bioepis. Amgen (i) maintained the allegations regarding the Roche Patents, but (ii) withdrew the allegations regarding the Psoriasis Patents, and (iii) added infringement allegations regarding three other manufacturing patents that were later dismissed.

144. The *Sandoz* decisions had a significant impact on the *Bioepis* case. On November 3, 2021, Amgen successfully used the Roche Patents to preclude biosimilar entry by Bioepis

when the *Bioepis* court entered judgment in favor of Immunex and against Bioepis on the claims for infringement of the Roche '182 Patent and '522 Patent. Bioepis was permanently enjoined from commercializing in the United States any product containing etanercept. Bioepis was also required to immediately destroy any Bioepis etanercept product that had been imported into the United States. The injunction terminates on April 24, 2029, once both the '182 Patent and the '522 Patent expire.

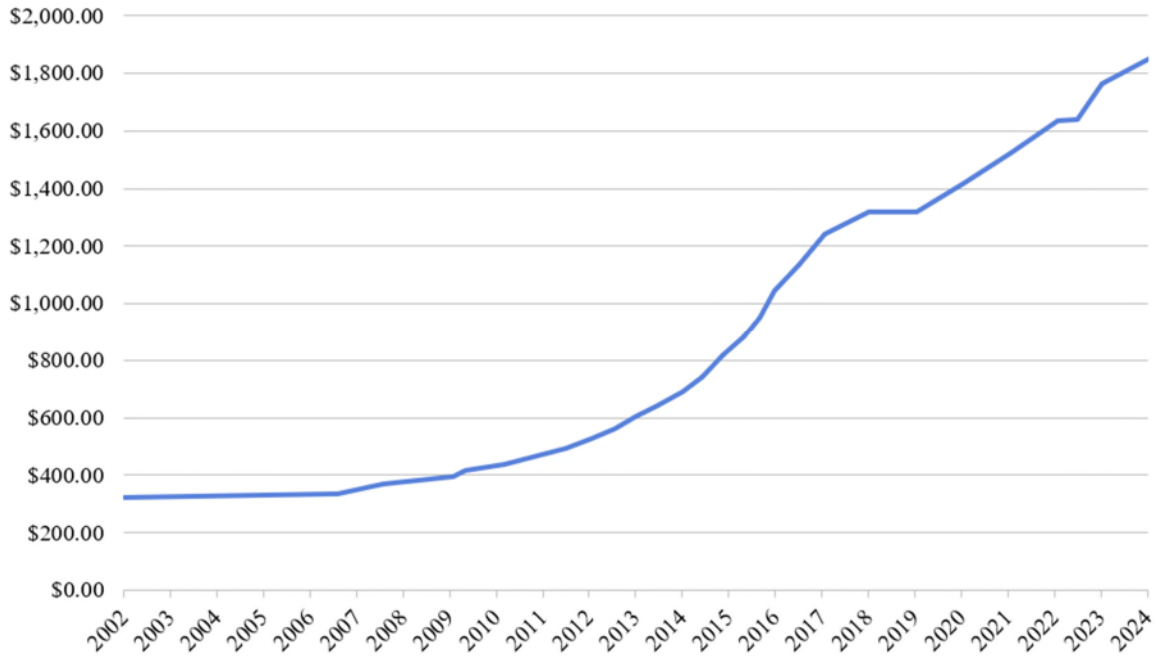
145. Once again, it was the Roche Patents that allowed Amgen to keep its competitor off the market and extend its Enbrel monopoly.

H. Amgen exploited its Enbrel monopoly with annual price hikes that helped the company secure more than $86 billion in net revenues.

146. Amgen capitalized on its monopolist position by continuously raising the per unit price of Enbrel.

147. A 2020 investigation of Amgen's pricing of Enbrel by the House of Representatives' Committee on Oversight and Reform found that, since acquiring the rights to Enbrel in 2002, Amgen raised its price 27 times, including by nearly 30% within one 12-month period. By 2020, a 50-mg dose of Enbrel cost $1,414 per unit, $5,556 per month, or $72,240 a year: a 457% increase from the date Amgen acquired it.

Figure 3. Price Per 50-mg Dose of Enbrel, 2002–2024[62]



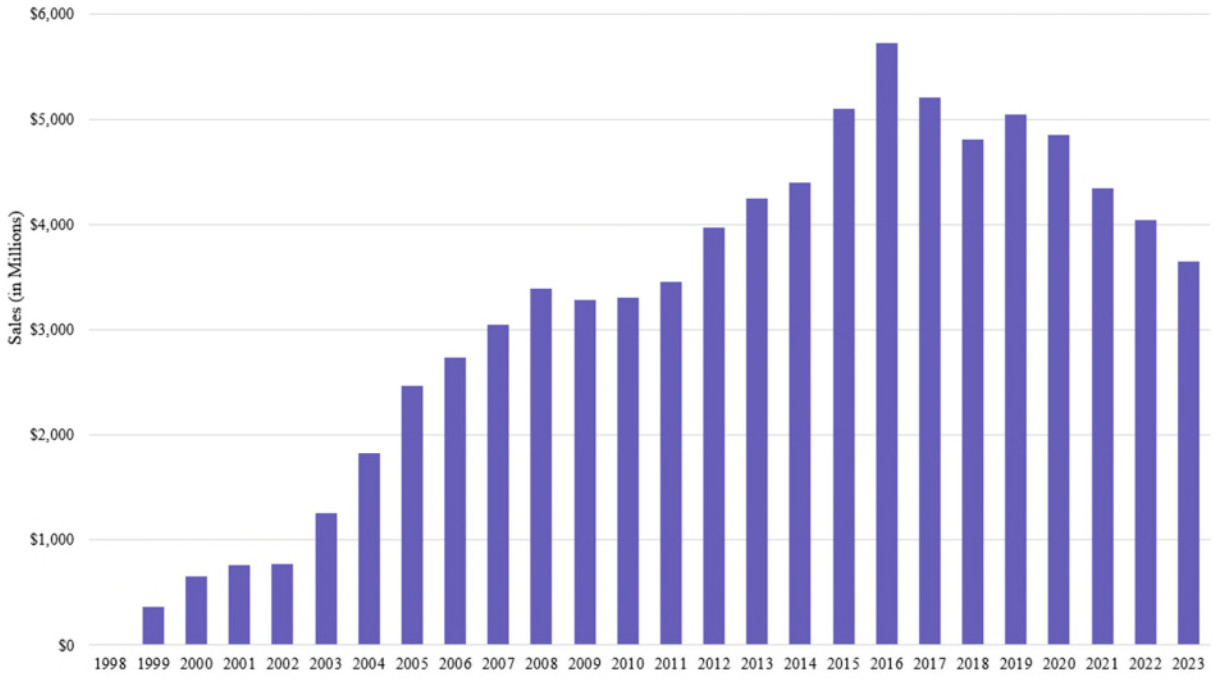
148. Since 2020, Amgen has increased the price of Enbrel at least six more times. A 50-mg dose of Enbrel now costs patients $7,401.83 per month: *643% more* than it cost when launched in 1998.

149. These price increases fueled Amgen's massive profits from Enbrel sales. Its Enbrel revenues increased every year from 2002 to 2016, culminating in $5.72 billion in 2016. One case study found that 100% of Enbrel's revenue growth between 2011 and 2021 came from price increases alone. And despite recent declines in prescription volumes, Amgen has continued to reap billions annually, profiting $3.65 billion in 2023.

150. All told, Amgen has grossed more than $86.33 billion in sales of Enbrel. And Enbrel remains one of Amgen's best-selling products both in the United States and worldwide, delivering nearly $3.7 billion in total sales in 2023.

[62] WAC per 50-mg dose of Enbrel for NDC 58406-0435-01 for 2002–2022 period and for NDC 58406-0021-01(pre-filled syringe) for 2023–2024 period.

Figure 4. U.S. Sales of Enbrel, 1998–2023



I. Amgen uses its exclusive license to the Brockhaus Patent Rights to unlawfully buttress and entrench its monopoly.

151. Amgen has successfully used the rights it acquired under the 2004 Exclusive License—the exclusive license rights to the Brockhaus Patents, the right to prosecute patents under them, and the right to bring enforcement actions—to unlawfully entrench and strengthen its monopoly, blocking biosimilar entry into the U.S. market for etanercept.

152. Were it not for Amgen's unlawful acquisition of those rights, and its later use of them to block biosimilar entry, one or more Enbrel biosimilar products would have entered the U.S. market no later than 2019, increasing competition and driving down prices. Amgen's ceaseless efforts to thwart such competition runs afoul of state and federal antitrust and consumer protection laws.

153. *First*, without Amgen's acquisition of exclusive rights in the 2004 Exclusive License, Roche would have retained the "co-exclusive" right to license the Brockhaus Patents to

another competitor or use them itself. Unable (under the law) to sell that highly valuable right to Amgen (a monopolist in the etanercept market), a reasonable company in the position of Roche would have monetized those rights by either launching its own biosimilar product or licensing another to enter the market.

154. *Second*, two sophisticated pharmaceutical companies, Sandoz and Bioepis, had invested significant time and money into developing and getting FDA approval for (in 2016 and 2019, respectively) biosimilar etanercept. A reasonable company in Roche's position would not simply sit on valuable, unused patent rights but instead would license them to a company who had demonstrated a commitment to investing in a competing biosimilar product—like Sandoz or Bioepis. Indeed, Roche already had several long-term manufacturing and other agreements with biosimilar companies, including Bioepis.

155. *Third*, were it not for Amgen's unlawful acquisition of the exclusive license to the Brockhaus Patents and the right to prosecute patents under them, the '182 and '522 Patents would likely never have issued or would have issued in a different form. When Roche controlled the applications, it prosecuted them for its development of work in connection with sequencing the p55 version of the human TNF receptors and *did not cover etanercept*. It was only after Amgen acquired the right to prosecute the applications that the applications were re-crafted to more clearly and directly protect etanercept, a p75 version of the human TNF receptors. If Amgen had not acquired patent prosecution rights, amended the claims to cover etanercept, and fought hard for years to secure issuance, it is highly doubtful that the '182 and '522 Patents—if they issued at all—would have protected etanercept. Amgen *relied solely* on the '182 and '522 Patents to successfully block biosimilar entry in the *Bioepis* and *Sandoz* cases. Absent Amgen's

unlawful acquisition of these patents to buttress and prolong its monopoly, multiple biosimilars could and would have entered the market before 2020.

156. Samsung would have launched its etanercept biosimilar, Erelzi, at least by August 13, 2019 (when the Psoriasis Patents expired), but potentially as early as August 16, 2016 (when the FDA granted final approval of Sandoz's aBLA).

157. Bioepis would have launched its etanercept biosimilar, Eticovo, at least by August 13, 2019, as well, but potentially as early as April 25, 2019 (when the FDA granted final approval of Bioepis's aBLA).

158. Amgen knew that biosimilar entry would have an immediate adverse effect on Enbrel sales. With multiple biosimilar entrants, "competition [would] intensif[y] rapidly, resulting in greater net price declines for both the reference and biosimilar products and a greater effect on product sales."[63]

159. Erelzi and Eticovo would likely have launched at Wholesale Acquisition Cost (WAC) prices 15%–37% lower than that of Enbrel[64] and captured 20%–25% of the etanercept market within one year of entry[65]—saving purchasers approximately $151–467 million in the

[63] Amgen, Inc., Annual Report (Form 10-K) at 18 (Feb. 27, 2024).

[64] *See* Amgen, *2020 Biosimilar Trends Report* at 14, 18 (Sept. 2020), https://www.amgenbiosimilars.com/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80723-2020-Amgen-Biosimilar-Trends-Report.pdf ("Amgen 2020 Biosimilar Trends Report") (reporting that "manufacturers are launching biosimilars at a WAC price that is generally 15% to 37% lower than the reference product WAC"); *see also* IQVIA Biosimilars Report at 2 (noting that price discounts for biosimilars "range significantly," but "appear to reflect prior assumptions of roughly 30% discounts").

[65] *See* Amgen 2020 Biosimilar Trends Report ("Within the first year, biosimilar share generally ranged from 20% to 25%."); *see also* IQVIA Biosimilars Report at 10 (indicating that earlier biosimilars achieved 25% share of molecule volume within the first year and 39% after two years, but also noting that two biosimilars launched in 2019 had achieved significantly higher first-year uptake of 38% and 42%).

first year alone.[66] Uptake of the etanercept biosimilars would have continued to increase over time, capturing approximately 75% of the market after three years, saving purchasers nearly $1 billion annually.[67] Had both biosimilar competitors launched on August 13, 2019, purchasers of etanercept collectively would have saved at least $3–4 billion to date.[68]

160. Amgen acted with the intent of keeping prices high—after all, Amgen itself acknowledges the extraordinary benefits of biosimilar entry. As Amgen has observed:

> Since the first biosimilar entered the US marketplace in 2015, 39 biosimilars have been approved, 22 of which have been launched. Biosimilars have gained significant share in the majority of therapeutic areas where they have been introduced. The US marketplace is poised to see further growth in the number of biosimilars approved and welcome many new biosimilars in the years to come. Additional competition may lead to significant savings for the healthcare system, and these savings can be deployed to newer, innovative treatments.[69]

161. Amgen admits that "[c]ompetitive mechanisms are in place to support biosimilar uptake" and that "[b]iosimilars have the potential to reduce healthcare costs by providing significant wholesale acquisition cost (WAC) and average sales price (ASP) savings at launch and through price competition, resulting in the opportunity for additional savings over time."[70] It notes that the "rate of biosimilar uptake is generally increasing over time" and that "first-to-

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[66] Based on Amgen's reported Enbrel sales of $5.05 billion for FY2019.

[67] *See* Amgen, *2022 Biosimilar Trends Report* at 14 (Oct. 2022), https://www.amgenbiosimilars.com/commitment/2022-Biosimilar-Trends-Report ("Amgen 2022 Biosimilar Trends Report") ("For therapeutic areas with biosimilars launched in the last 3 years, the average share was 75%.").

[68] A 30% WAC discount and market share of 25% after the first year and increasing to 60% the fifth year would result in a savings of $2.66B in total sales.

[69] Amgen 2022 Biosimilar Trends Report at 6.

[70] *Id.* at 6, 12.

launch biosimilars tend to capture a greater portion of the segment compared to later entrants."[71] It notes that, for "therapeutic areas with biosimilars launched in the last 3 years, the average share was 75%" and "the cumulative savings in drug spend for classes with biosimilar competition is estimated to have been $21 billion over the past 6 years."[72]

162. The fact that Amgen has been able to block biosimilar entry for etanercept since the late 2010s or early 2020s is egregious given that entry of a biosimilar Enbrel should and likely would have been the first biosimilar drug in the extraordinarily costly autoimmune therapeutic area. In 2021, global sales of autoimmune drugs totaled more than $40 billion. As Amgen has remarked about the autoimmune space, "the planned launches of biosimilars to Humira [another autoimmune drug used to treat similar conditions as Enbrel] in 2023 could be a pivotal moment."[73] But that pivotal moment could, and should, have first occurred with Enbrel. And as Amgen has admitted, "More biosimilars to treat autoimmune conditions will be coming to market this decade, offering an opportunity to inject competition and reduce healthcare costs."[74]

163. The absence of a biosimilar for Enbrel in the U.S. is particularly disturbing considering that a biosimilar product was first developed and approved *eight years ago*. Despite companies with biosimilar versions of Enbrel having undergone a thorough FDA approval process, they remain unable to enter the market.

164. But because of the unlawful monopoly conferred by the '182 and '522 Patents, purchasers continue to be overcharged hundreds of millions of dollars per year for etanercept

[71] *Id.* at 14.

[72] *Id.* at 14–15.

[73] *Id.* at 24.

[74] *Id.*

purchases. For at least 26 years—from November 1998 (Enbrel's launch) through the filing of this complaint—Amgen has enjoyed exclusive sales of Enbrel, and if not enjoined, will continue to do so until 2029.

165. In sum, Amgen knowingly and willfully acquired the exclusive license to Roche's patent applications and subsequent patents to delay competition from would-be etanercept biosimilar competitors and to further entrench its etanercept monopoly. Amgen's acquisition of the Roche Patents and patent applications was for the purpose, and has had the consequence of, unlawfully extending and maintaining Amgen's monopoly in the market for etanercept in the United States.

VI. CLASS ALLEGATIONS

166. The plaintiffs, on behalf of themselves and the putative class members, seek damages (measured as overcharges) against Amgen based on their allegations of anticompetitive conduct in the market for etanercept in the United States.

167. The plaintiffs bring this action on behalf of themselves and, pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), and 23(b)(3), as representatives of the class defined as:

> All end payors (including any assignees of such end payors) in the United States and its territories who purchased and/or paid all or part of the purchase price of Enbrel from July 2020 until the anticompetitive effects of the defendants' conduct cease ("class period").

168. Excluded from the class are the defendants and any of their officers, directors, management, employees, subsidiaries, and affiliates.

169. Also excluded from the class are: (1) the government of the United States and all agencies thereof, and (2) all state or local governments and all agencies thereof.

170. Class members are so numerous and geographically dispersed that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together.

171. The plaintiffs' claims are typical of those of the class members. The same wrongful conduct damaged the plaintiffs and all class members—i.e., they paid and will pay artificially inflated prices for etanercept and were deprived of earlier and more robust competition from cheaper biosimilar versions of etanercept because of Amgen's wrongful conduct.

172. The plaintiffs will fairly and adequately protect and represent the class's interests. The plaintiffs' interests are coincident with, and not antagonistic to, those of the other class members.

173. Counsel representing the plaintiffs are experienced in the prosecution of antitrust class action litigation and have extensive experience with class action antitrust litigation involving pharmaceutical products.

174. Questions of law and fact common to the class members predominate over questions that may affect only individual class members because Amgen has acted on grounds generally applicable to the entire class. This conduct renders appropriate overcharge damages with respect to the class as a whole. Such generally applicable conduct is inherent to Amgen's wrongful actions.

175. Questions of law and fact common to the proposed class include:

a. whether Amgen willfully and improperly maintained monopoly power over etanercept in the United States;

b. whether Amgen intentionally acquired the exclusive license to the Roche Patents and Patent Applications to unlawfully delay competition and to unlawfully maintain its monopoly over etanercept;

c. whether Amgen unlawfully used the Roche Patents to delay etanercept biosimilar competition;

d. whether Amgen unlawfully excluded competitors and potential competitors from the market for etanercept;

e. whether Amgen unlawfully delayed or prevented manufacturers of etanercept biosimilars from coming to market in the United States;

f. whether Amgen improperly maintained monopoly power by delaying biosimilar entry;

g. whether the law requires a definition of a relevant market when direct proof of monopoly power is available, and if so, the definition of the relevant market;

h. whether Amgen's activities as alleged herein have substantially affected interstate commerce;

i. whether, and if so to what extent, Amgen's conduct caused antitrust injury (i.e., overcharges) to the plaintiffs and the class members; and

j. the quantum of aggregate overcharge damages to the plaintiffs and class members.

176. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would require. The benefits of proceeding through the class mechanism—including providing injured persons or entities with a method for obtaining redress on claims that they could not practicably pursue on an individual basis—substantially outweigh potential difficulties in management of this class action.

177. Amgen's anticompetitive conduct has imposed and will continue to impose (unless the plaintiffs obtain equitable relief) a common antitrust injury on the plaintiffs and all class members. Amgen's anticompetitive conduct and its relationships with the class members have been substantially uniform. Amgen has acted and refused to act on grounds that apply to the

class generally, and injunctive and other equitable relief is appropriate respecting the class as a whole.

178. The plaintiffs know of no special difficulty in litigating this action that would preclude its maintenance as a class action.

VII. MARKET POWER AND MARKET DEFINITION

179. The relevant geographic market is the United States and its territories.

180. The relevant product market is etanercept.

181. At all times relevant to this civil action, Amgen had monopoly power in the market for etanercept in the United States.

A. Direct evidence demonstrates Amgen's market power.

182. *Supracompetitive prices*. At all times relevant to this civil action, Amgen charged supracompetitive prices for Enbrel—i.e., prices that were and are markedly higher than those Amgen could have charged had there been biosimilar competition for etanercept. Amgen also steadily *increased* the price of Enbrel over the years.

183. From 1998 to the present, Amgen *never* lowered Enbrel prices or lost sales volume in response to the pricing of other drugs, even though other biologic products were available in the U.S. to treat rheumatoid arthritis, psoriasis, PsA, ankylosing spondylitis, and JIA, indicating that its sales are not constrained by any other products.

184. *Supracompetitive profit margins.* At all times relevant to this action, Amgen enjoyed extraordinarily high profit margins from the sale of Enbrel.

185. *Combination patent protection and other barriers*. From Enbrel's 1998 launch through the filing of this complaint, Amgen has enjoyed and continues to enjoy patent protection for etanercept. As a result, Amgen has the power to exclude competition from etanercept biosimilars.

186. *Lack of interchangeability*. Etanercept is not readily interchangeable with other treatments for rheumatoid arthritis, psoriasis, PsA, ankylosing spondylitis, or JIA. Etanercept is a unique treatment for these diseases, ostensibly offering advantages over other available treatments for these conditions.

187. *Biosimilar competition*. Recent reports regarding biosimilars confirm that biosimilar competition has a significant effect in lowering price among equally effective therapies.

188. Recent biosimilars have achieved high market volume share, reaching more than 60% of a given biologic's volume within the first three years on the market. The introduction of biosimilars frequently leads to higher utilization of the treatment as lower costs improve patient access.

189. Introduction of lower cost biosimilars precipitates reductions in overall drug costs per unit at invoice prices over time. Indeed, such competition typically lowers the per unit cost of both the brand and biosimilar drug. Costs are down between 18% and 50% per unit for drugs with biosimilars.

190. Amgen, in its 2022 Biosimilar Trends report, admitted that biosimilar entrants are typically successful at taking market share from the reference biologic drug. Amgen's report states: "Biosimilars have gained significant share in the majority of therapeutic areas where they have been introduced."[75] Amgen further remarked: "For therapeutic areas with biosimilars launched in the last 3 years, the average share was 75%," and "[f]or therapeutic areas with biosimilars launched prior to 2019, the average share after 3 years was 39%."[76]

[75] Amgen 2022 Biosimilar Trends Report at 14.

[76] *Id.*

191. A 2022 study published in the *Journal of the American Medical Association* found that "[b]iosimilars in the US that entered the market more recently were estimated to experience a faster uptake (as measured by the market share 1 year after launch). . . ."[77]

192. The effects of biosimilar competition in the U.S. market for etanercept would also have substantial downward pressure on the price of etanercept.

193. Direct evidence shows that Amgen has monopoly power over the sale of etanercept in the United States and that entry of a biosimilar etanercept would cause significant downward pressure on price, resulting in more affordable and accessible etanercept products.

B. Indirect evidence demonstrates Amgen's market power.

194. To the extent the plaintiffs are legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, the relevant product market is the sale of etanercept in the United States and has, thus far, consisted solely of Enbrel. Biosimilar versions of etanercept will also be in the relevant market once they are available. At all relevant times, Amgen's market share in the market was and remains 100%.

195. Amgen, at all relevant times, enjoyed high barriers to entry with respect to competition in the product market of etanercept due, in large part, to legally and illegally created patent protections.

196. Enbrel does not exhibit significant, positive cross-elasticity of demand with any other medication. The existence of non-etanercept products that may be used to treat similar indications as etanercept has not constrained Amgen's ability to raise or maintain Enbrel prices

[77] David L. Carl, Yannic Laube & Miguel Serra-Burriel, *Comparison of Uptake and Prices of Biosimilars in the US, Germany, and Switzerland*, 5 JAMA Netw. Open 1, 6 (2022).

without losing substantial sales. As a result, those other drug products do not occupy the same relevant antitrust market as Enbrel.

197. Amgen needed to control only etanercept, and no other products, to maintain a supracompetitive price for Enbrel while preserving all or virtually all its sales. Only market entry of a competing, biosimilar etanercept would undermine Amgen's ability to keep Enbrel prices high without losing substantial sales.

198. Indirect evidence shows that Amgen had monopoly power in an antitrust market of the sale of etanercept in the United States.

VIII. MARKET EFFECTS AND CLASS DAMAGES

199. In the absence of the anticompetitive conduct alleged above, multiple manufacturers would have entered the market with etanercept biosimilars at least by August 2019, and potentially as early as August 2016.

200. Instead, Amgen willfully and unlawfully maintained its monopoly power in the market for etanercept through the following an anticompetitive scheme: (i) Amgen unlawfully acquired an exclusive license to the Roche Patent rights; and (iii) Amgen used those patent rights to buttress and entrench its monopoly and delay competition from would-be etanercept biosimilar competitors. These acts, individually and in combination, were anticompetitive.

201. Amgen's scheme had, and continues to have, the purpose and effect of preventing biosimilar competition, permitting Amgen to maintain supracompetitive monopoly prices for Enbrel and enabling Amgen to sell Enbrel without competition. Absent Amgen's conduct, biosimilar versions of etanercept would have been available sooner.

202. Competition among drug manufacturers enables all purchasers of their drugs to buy biosimilar versions of the drugs at substantially lower prices and/or to buy the reference biologic products at reduced prices. Consequently, reference (i.e., brand) biologic manufacturers

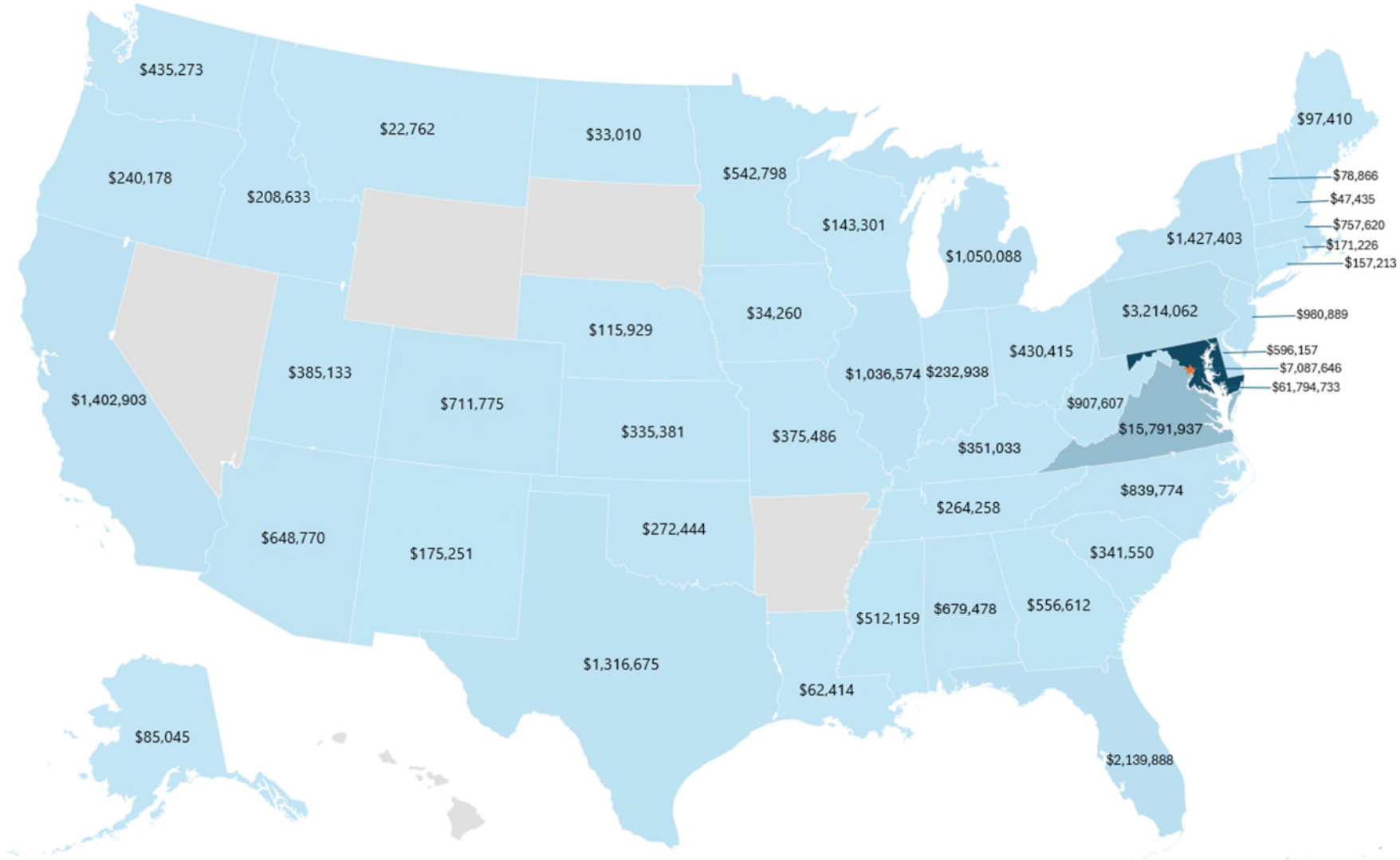
have a strong incentive to delay biosimilar competition. Purchasers experience substantial cost inflation from that delay.

203. If competition from biosimilar manufacturers had not been restrained and forestalled in the case of etanercept, end payers like the plaintiffs and class members would have paid less for etanercept by: (i) purchasing, and providing reimbursement for, biosimilar versions of etanercept instead of the more expensive Enbrel, and (ii) purchasing, and providing reimbursement for, Enbrel at lower prices.

204. As a result, Amgen's conduct has forced and will continue to force the plaintiffs and class members to pay more for Enbrel and biosimilar etanercept than they would have paid absent Amgen's misconduct.

205. Between 2021 and 2023, CareFirst has purchased Enbrel for its members in 45 states and the District of Columbia, and paid more than $109 million for members' Enbrel prescriptions. The breakdown by state is shown in the figure below.

Figure 5. CareFirst's Enbrel Purchases by State, 2021–2023



IX. ANTITRUST IMPACT

206. The effect of Amgen's conduct is to net Amgen billions of dollars in revenue at the expense of end payers, including the plaintiffs and class members, who will pay hundreds of millions, if not billions, of dollars in unlawful overcharges.

207. During the relevant period, the plaintiffs and class members purchased substantial amounts of Enbrel indirectly from Amgen.

208. As a direct and proximate result of Amgen's anticompetitive conduct, the plaintiffs and class members have paid and will continue to pay supracompetitive prices for etanercept because (1) the price of Enbrel was and is artificially inflated by Amgen's anticompetitive conduct, and (2) the plaintiffs and class members were and are deprived of the opportunity to purchase lower-priced biosimilar versions of etanercept.

209. As a result, the plaintiffs and class members have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

210. The overcharges resulting from Amgen's conduct are directly traceable through the pharmaceutical distribution chain to the plaintiffs and other class members. Amgen first sells Enbrel to wholesalers based on Enbrel's listed WAC, minus applicable discounts. Wholesalers then sell Enbrel to specialty pharmacies, which in turn sell it to consumers. In this short chain of distribution, drug products are not altered or incorporated into other products. Each drug purchase is documented and closely tracked by pharmacies, pharmacy benefit managers, and third-party payers (such as insurers and health and welfare funds). The products and their prices are thus directly traceable from manufacturer to consumer.

X. IMPACT ON INTERSTATE COMMERCE

211. Amgen's efforts to monopolize and restrain competition in the market for etanercept have substantially affected interstate and foreign commerce.

212. At all material times, Amgen manufactured, sold, and shipped substantial amounts of Enbrel across state lines in an uninterrupted flow of commerce across state and national lines throughout the United States.

213. At all material times, Amgen transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Enbrel.

214. To further its monopolization and restraint on competition in the market for etanercept, Amgen used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. Amgen engaged in illegal activities, as charged herein, within the flow of—and substantially affecting—interstate commerce, including in this district.

XI. FEDERAL CLAIMS FOR RELIEF

COUNT ONE

MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2) SEEKING DECLARATORY AND INJUNCTIVE RELIEF

215. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

216. At all relevant times, Amgen possessed and continues to possess substantial market power (i.e., monopoly power) in the market for etanercept in the United States. Amgen possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for etanercept.

217. Amgen's market power is coupled with strong regulatory and contractual barriers to entry.

218. At all relevant times, Amgen knowingly, willfully, and improperly maintained its monopoly power in the U.S. market for etanercept from as early as 2016 until the present through restrictive and exclusionary conduct, rather than through growth or development resulting from a superior product, business acumen, or historic accident, and thereby injured the plaintiffs and class members. Amgen's conscious objective was to further its dominance and monopoly power in the market for etanercept in the United States.

219. Amgen knowingly, willfully, and improperly maintained its monopoly power and substantially reduced and harmed competition in the market for etanercept in the United States by:

- wrongfully acquiring an exclusive license to the Roche Patents and Patent Applications to delay and/or prevent would-be competitors from developing etanercept biosimilars and entering the market; and
- using and/or enforcing the wrongfully acquired exclusive license to the Roche Patents to unlawfully delay competition from would-be etanercept biosimilar competitors, including Sandoz and Bioepis.

220. Amgen's monopoly power over etanercept should have expired no later than 2019—and as early as 2016—when Amgen's patents had expired and biosimilar entered the market. Instead, due to its unlawful acquisition and enforcement of the Roche Patent rights, Amgen's monopoly power will extend at least five years too long, until Amgen is enjoined or the Roche Patents expire on April 24, 2029. As a result of Amgen's unlawful anticompetitive scheme, no other entity currently sells biosimilar etanercept in the United States. This is true even though the FDA has already approved two etanercept biosimilars.

221. The goal, purpose, and effect of Amgen's overarching anticompetitive scheme was to delay and/or block etanercept biosimilars from entering the market, maintain its monopoly in that market, and maintain its supracompetitive prices for Enbrel.

222. Amgen's anticompetitive scheme substantially reduced and harmed competition in the relevant market and was an unreasonable restraint on trade.

223. Had Amgen competed on the merits, instead of unlawfully maintaining its monopoly in the market for etanercept, one or more etanercept biosimilars would have been available by no later than 2019, and as early as 2016. The plaintiffs and class members would have substituted the lower-priced etanercept biosimilar products for the higher-priced brand Enbrel (or purchased Enbrel at lower prices) for some or all their etanercept requirements. As a result, they would have paid substantially lower prices for etanercept.

224. To the extent that Amgen is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for its exclusionary conduct that outweighs that conduct's harmful effects. Even if there were some conceivable justifications that Amgen were permitted to assert, Amgen's conduct is and was broader than necessary to achieve such a purpose.

225. Amgen's anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiffs and class members throughout the United States. The plaintiffs' and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Enbrel from Amgen; (b) paying higher prices for etanercept than they would have paid in the absence of Amgen's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar etanercept at a price substantially lower than what they were forced to pay

for Enbrel. These injuries are of the type that the antitrust laws were designed to prevent, and they flow from that which makes Amgen's conduct unlawful.

226. The plaintiffs and the class members are the proper entities to bring a case concerning Amgen's unlawful anticompetitive scheme.

227. The plaintiffs and class members have been injured, and unless Amgen's unlawful conduct is enjoined, the plaintiffs and class members will continue to be injured, in their businesses and property, as a direct and proximate result of Amgen's continuing monopolization in violation of Section 2 of the Sherman Act.

228. Pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), the plaintiffs and the class members seek a declaratory judgment that Amgen's conduct seeks to prevent competition as described in the preceding paragraphs violates § 2 of the Sherman Act.

229. Pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, the plaintiffs and class members further seek equitable and injunctive relief to correct for the anticompetitive market effects Amgen's unlawful conduct caused and to ensure that similar anticompetitive conduct does not occur in the future.

XII. STATE CLAIMS FOR RELIEF

COUNT TWO

MONOPOLIZATION AND MONOPOLISTIC SCHEME UNDER STATE LAW

230. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

231. Count Three is pleaded on behalf of the plaintiffs and class members under the antitrust laws of each jurisdiction identified below.

232. Count Three arises from Amgen's exclusionary, anticompetitive scheme that was designed to create and maintain Amgen's improper monopoly over etanercept and exclude or substantially exclude its biosimilars from the market.

233. The essential elements of each antitrust claim in Count Three are the same. The above-alleged conduct that violates the Sherman Act will, if proven, establish a claim under each of the laws cited below.

234. At all relevant times, Amgen possessed and continues to possess substantial market power (i.e., monopoly power) in the market for etanercept. Amgen possessed and continues to possess the power to control prices in, prevent prices from falling in, and exclude competitors from the U.S. market for etanercept.

235. Through its overarching anticompetitive scheme, as alleged above, Amgen willfully maintained its monopoly power in the market for etanercept in the United States after 2004, when it obtained its exclusive license from Roche, using restrictive or exclusionary conduct, rather than by means of a superior product, business acumen, or historic accident, and thereby injured the plaintiffs and the class members. Amgen engaged in its anticompetitive scheme with the specific intent to maintain its monopoly in the market for etanercept in the United States.

236. Amgen accomplished its anticompetitive scheme by: (i) wrongfully acquiring the rights to the Roche Patents; and (iii) using the wrongfully acquired Roche Patents to unlawfully delay competition from would-be etanercept biosimilar competitors.

237. The goal, purpose, and effect of Amgen's overarching anticompetitive scheme was to delay and/or block etanercept biosimilars from entering the market, extend Amgen's monopoly in that market, and maintain its supracompetitive prices for Enbrel.

238. Amgen's anticompetitive scheme substantially reduced and harmed competition in the relevant market and was an unreasonable restraint on trade.

239. Amgen's anticompetitive scheme directly impacts and disrupts commerce within each jurisdiction below.

240. Had Amgen competed on the merits, instead of unlawfully maintaining its monopoly in the market for etanercept, one or more etanercept biosimilars would have been available at least by August 13, 2019 (the date the Psoriasis Patents expired), but potentially as early as August 16, 2016. The plaintiffs and class members would have substituted the lower-priced etanercept biosimilars for the higher-priced brand Enbrel (or paid less for Enbrel) for some or all their etanercept requirements. As a result, they would have paid substantially lower prices for etanercept.

241. During the class period, Enbrel, manufactured and sold by Amgen, was shipped into each state and was sold to or paid for by the plaintiffs and the class.

242. During the class period, in connection with the purchase and sale of Enbrel, money changed hands and business communications and transactions occurred in each state.

243. Amgen's conduct as set forth in this Complaint had substantial effects on intrastate commerce in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic Enbrel to end payors purchasing inside each respective state. This impairment of competition directly impacts and disrupts commerce within each state.

244. Amgen's anticompetitive activities have directly, foreseeably, and proximately caused injury to the plaintiffs and class members throughout the United States. The plaintiffs' and class members' injuries consist of: (a) being denied the opportunity to purchase lower-priced Enbrel from Amgen; (b) paying higher prices for etanercept than they would have paid in the

absence of Amgen's unfair, illegal, and deceptive conduct; and (c) being denied the opportunity to purchase biosimilar etanercept at prices substantially lower than what they were forced to pay for Enbrel. These injuries are of the type that the laws of the jurisdictions below were designed to prevent, and they flow from that which makes Amgen's conduct unlawful.

245. The plaintiffs and class members are the proper entities to bring a case concerning Amgen's unlawful anticompetitive scheme.

246. The defendants are jointly and severally liable for all damages suffered by the plaintiffs and the class members.

247. By engaging in the foregoing conduct, Amgen intentionally and flagrantly maintained its monopoly power over etanercept in the United States in violation of the following state laws:

a. Ala. Code § 8-10-3 with respect to the plaintiffs' and class members' purchases in Alabama.

b. Ariz. Arizona Rev. Stat. §§ 44-1401, *et seq*., including Ariz. Rev. Stat. § 44-1403, with respect to the plaintiffs' and class members' purchases in Arizona.

c. Cal. Bus. & Prof. Code §§ 16700, *et seq*., and §§ 17200, *et seq*., with respect to the plaintiffs' and class members' purchases in California.

d. Col. Rev. Stat. Ann. §§ 6-4-105, *et seq*., wit respect to the plaintiffs' and class members' purchases in Colorado.

e. Conn. Gen. Stat. §§ 35-24, *et seq*., with respect to the plaintiffs' and class members' purchases in Connecticut.

f. D.C. Code §§ 28-4501, *et seq*., with respect to the plaintiffs' and class members' purchases in the District of Columbia.

g. Fla. Stat. §§ 501.201, *et seq*., with respect to the plaintiffs' and class members' purchases in Florida.

h. Haw. Rev. Stat. §§ 480-13.3, *et seq.*, with respect to class members' purchases in Hawaii.

i. 740 Ill. Comp. Stat. 10/1, *et seq*., including 740 Ill. Comp. Stat. 10/3, with respect to the plaintiffs' and class members' purchases in Illinois.

j. Iowa Code §§ 553.1 *et seq*., including Iowa Code § 553.5, with respect to the plaintiffs' and class members' purchases in Iowa.

k. Kan. Stat. Ann. §§ 50-101, *et seq*., including Kan. Stat. Ann. § 50-132, with respect to the plaintiffs' and class members' purchases in Kansas.

l. Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq*., including Me. Rev. Stat. Ann. tit. 10, §1102, with respect to the plaintiffs' and class members' purchases in Maine.

m. Md. Code Com. Law § 11-201, *et seq*., including Md. Code Com. Law § 11-204, with respect to the plaintiffs' and class members' purchases in Maryland.

n. Mich. Comp. Laws Ann. §§ 445.771, *et seq*., with respect to the plaintiffs' and class members' purchases in Michigan.

o. Minn. Stat. Ann. §§ 325D.49, *et seq*., including Minn. Stat. Ann. § 325D.52 and Minn. Stat. Ann. § 8.31, *et seq*., with respect to the plaintiffs' and class members' purchases in Minnesota.

p. Miss. Code Ann. §§ 75-21-3, *et seq*., with respect to the plaintiffs' and class members' purchases in Mississippi.

q. Neb. Code Ann. §§ 59-801, *et seq*., including Neb. Code Ann. § 59-802, with respect to the plaintiffs' and class members' purchases in Nebraska.

r. Nev. Rev. Stat. Ann. §§ 598A.010, *et seq*., including Nev. Rev. Stat. Ann. § 598A.060, with respect to class members' purchases in Nevada.

s. N.H. Rev Stat. Ann. §§ 356.1, *et seq*., including N.H. Rev. Stat. Ann. § 356.3, with respect to the plaintiffs' and class members' purchases in New Hampshire.

t. N.M. Stat. Ann. §§ 57-1-1, *et seq*., including N.M. Stat. Ann. § 57-1-2, with respect to the plaintiffs' and class members' purchases in New Mexico.

u. N.Y. Gen. Bus. Law §§ 340, *et seq*., with respect to the plaintiffs' and class members' purchases in New York.

v. N.C. Gen. Stat. Ann. §§ 75-1, *et seq*., including N.C. Gen. Stat. Ann. § 75-2.1, with respect to the plaintiffs' and class members' purchases in North Carolina.

w. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, including N.D. Cent. Code §§ 51-08.1-03, with respect to the plaintiffs' and class members' purchases in North Dakota.

x. Or. Rev. Stat. §§ 646.705, *et seq.*, including Or. Rev. Stat. §§ 646.730, with respect to the plaintiffs' and class members' purchases in Oregon.

y. 10 L.P.R.A. §§ 257, *et seq.*, with respect to class members' purchases in Puerto Rico.

z. R.I. Gen. Laws §§ 6-36-1, *et seq.*, including R.I. Gen. Laws §§ 6-36-5, with respect to the plaintiffs' and class members' purchases in Rhode Island.

aa. S.D. Codified Laws §§ 37-1-3.1, *et seq.*, including S.D. Codified Laws §§ 37-1-3.2, with respect to class members' purchases in South Dakota.

bb. Tenn. Code Ann §§ 47-25-101, *et seq.*, with respect to the plaintiffs' and class members' purchases in Tennessee.

cc. Utah Code Ann. §§ 76-10-3101, *et seq.*, including Utah Code Ann. §§ 76-10-3104, with respect to purchases in Utah by class members that are Utah residents or citizens.

dd. Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*, with respect to the plaintiffs' and class members' purchases in Vermont.

ee. W.Va. Code §§ 47-18-1, *et seq.*, including § 47-18-4, with respect to the plaintiffs' and class members' purchases in West Virginia.

ff. Wis. Stat. §§ 133.01, *et seq.*, including Wis. Stat. §§ 133.04, with respect to the plaintiffs' and class members' purchases in Wisconsin.

248. As a result of the unlawful and anticompetitive conduct described above, the plaintiffs and/or members of the class paid artificially inflated prices for Enbrel, in each of these listed jurisdictions.

COUNT THREE

VIOLATIONS OF STATE CONSUMER PROTECTION LAWS

249. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

250. As described above, Amgen has engaged and continues to engage in unfair competition or unfair, unconscionable, deceptive, and/or fraudulent conduct, acts, or practices in violation of the state consumer protection statutes set forth below. As a direct and proximate result of Amgen's anticompetitive, deceptive, unfair, unconscionable, and/or fraudulent conduct, the plaintiffs have been and continue to be deprived of the opportunity to purchase lower-priced biosimilar versions of etanercept.

251. Amgen established, maintained, and/or used a monopoly, or attempted to establish a monopoly, and to restrain trade or commerce in the U.S. market for etanercept. A substantial part of this conduct occurred within each jurisdiction identified below. Amgen intended to injure competitors and exclude or substantially lessen competition. Amgen intended to injure consumers by unlawfully reaping supracompetitive profits.

252. By unlawfully delaying the entry of etanercept biosimilars, Amgen, as a supplier, engaged in a fraudulent or deceptive act or practice in connection with a consumer transaction.

253. Amgen's conduct constitutes consumer-oriented deceptive acts or practices that resulted in consumer injury and broad adverse impact on the public at large. Amgen's conduct thereby harmed consumers' interest in an honest marketplace where economic activity is conducted in a competitive manner.

254. Amgen withheld material facts and information from the plaintiffs and class members, including that Amgen was unlawfully excluding manufacturers of biosimilar etanercept from the market and monopolizing the market for etanercept (and thereby profiting from the resulting supracompetitive prices that the plaintiffs and class members who purchased or reimbursed purchases of Enbrel paid).

255. Amgen's conduct was willful and knowing. Amgen intended to deceive the plaintiffs and class members regarding the nature of its actions within the stream of commerce in each jurisdiction below.

256. Amgen's acts, omissions, misrepresentations, practices, and/or non-disclosures constituted a common, continuous, and continuing course of conduct of deceptive and unfair competition by means of unfair, unlawful, and/or fraudulent business acts or practices.

257. The plaintiffs and class members purchased (or reimbursed their members for purchases of) etanercept primarily for personal, family, or household purposes.

258. The plaintiffs and class members who do not profit from purchasing etanercept or from reimbursing their members for purchases of etanercept are "consumers" under the consumer protection laws of the jurisdictions below.

259. There was and is a gross disparity between the price that the plaintiffs and class members paid for etanercept and the value they received given that less expensive biosimilar versions of etanercept should have been available and would have been but for Amgen's unlawful conduct.

260. As a direct and proximate result of Amgen's unlawful conduct, the plaintiffs and class members have been injured and are threatened with continued injury.

261. As a direct and proximate result of Amgen's unfair, unconscionable, deceptive, and fraudulent conduct in violation of the state consumer protection statutes listed below, the plaintiffs and class members were denied the opportunity to purchase lower-priced etanercept biosimilars and paid higher prices for Enbrel than they would otherwise have paid.

262. The gravity of harm from Amgen's unlawful conduct significantly outweighs any conceivable utility from that conduct. The plaintiffs and class members could not reasonably have avoided injury from Amgen's conduct.

263. Amgen's unlawful conduct substantially affected the trade and commerce of each jurisdiction in which etanercept was sold.

264. Amgen's unfair and deceptive acts described above were knowing, willful, and unconscionable and constitute violations or flagrant violations of the following unfair trade practices and consumer protection statutes:[78]

[78] Upon completion of the requisite statutory notices, the plaintiffs intend to amend this complaint to add claims under the following state statutes:

a. Ala. Code §§ 8-19-10(e), *et seq.*, with respect to the plaintiffs' and class members' purchases in Alabama.

b. Alaska Stat. §§ 45.50.471, *et seq.*, with respect to the plaintiffs' and class members' purchases in Alaska.

c. California Consumer Legal Remedies Act - Cal. Civ. Code §§ 1750 et seq., with respect to the plaintiffs' and class members' purchases in California.

d. Ga. Stat. §§ 10-1-390, *et seq.*, with respect to the plaintiffs' and class members' purchases in Georgia.

e. Ind. Code Ann. §§ 24-5-0.5-3, *et seq.*, with respect to the plaintiffs' and class members' purchases in Indiana.

f. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to the plaintiffs' and class members' purchases in Maine.

g. Mass. Gen. Laws ch. 93A, §§ 1, *et seq.*, with respect to the plaintiffs' and class members' purchases in Massachusetts.

h. Tex. Bus. & Com. Code §§ 17.41, *et seq.*, with respect to the plaintiffs' and class members' purchases in Texas.

i. West Va. Code §§ 46A-6-101, *et seq.*, with respect to the plaintiffs' and class members' purchases in West Virginia.

j. Wyo. Stat. §§ 40-12-100, *et seq.*, with respect to class members' purchases in Wyoming.

265. As a result of the unfair and deceptive conduct described above, the plaintiffs and/or members of the class paid artificially inflated prices for Enbrel, in each of these listed jurisdictions.

1. Ariz. Rev. Stat. §§ 44-1521 *et seq*. (with respect to the plaintiffs' and class members' purchases of etanercept in Arizona)

266. Section 44-1522 of the Arizona Revised Statutes provides:

> The act, use or employment by any person of any deception, deceptive or unfair act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely on such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

267. As set forth in detail above, Amgen violated § 44-1522 of the Arizona Revised Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

268. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

269. The plaintiffs' and class members' injuries are of the type that § 44-1522 of the Arizona Revised Statutes was intended to prevent.

270. The plaintiffs are entitled to bring this action for damages pursuant to § 44-1533 of the Arizona Revised Statutes.

271. The plaintiffs are entitled to recover actual damages and punitive damages because Amgen's conduct was wanton, was reckless, shows spite or ill will, and demonstrates a reckless indifference to the interests of others.

2. Ark. Code Ann. §§ 4-88-101 *et seq*. (with respect to class members' purchases in Arkansas)

272. Section 4-88-107 of the Arkansas Code provides as follows:

> (a) Deceptive and unconscionable trade practices made unlawful and prohibited by this chapter include, but are not limited to, the following: . . .
>
> (10) Engaging in any . . . unconscionable, false, or deceptive act or practice in business, commerce, or trade; . . .
>
> (b) The deceptive and unconscionable trade practices listed in this section are in addition to and do not limit the types of unfair trade practices actionable at common law or under other statutes of this state.

273. As set forth in detail above, Amgen violated § 4-88-107 of the Arkansas Code by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

274. As a direct and proximate result of Amgen's conduct, class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

275. The class members' injuries are of the type that § 4-88-107 of the Arkansas Code was intended to prevent.

276. The plaintiffs are entitled to bring this action for damages pursuant to § 4-88-113 of the Arkansas Code.

277. Class members are entitled to recover their actual damages, along with reasonable attorneys' fees, pursuant to § 4-88-113(f) of the Arkansas Code.

3. Colo. Rev. Stat. § 6-1-105, *et seq.* (with respect to the plaintiffs' and class members' purchases in Colorado)

278. Colorado Revised Stature § 6-1-105(1) (as amended and effective as of August 7, 2024) provides that "(1) a person engages in a deceptive trade practice when, in the course of the person's business, vocation, or occupation, the person…" "(rrr) Either knowingly or recklessly engages in any unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent act or practice…"

279. The Colorado Revised Statute is clear that the "deceptive trade practices listed in this section are in addition to *and do not limit the types of unfair trade practices actionable at common law or under other statutes of this state*." Colo. Rev. Stat. § 6-1-105(3).

280. As alleged above in Count Two, the Colorado Revised Statute § 6-4-105 specifically provides that it is "illegal for any person to monopolize, attempt to monopolize, or combine or conspire with any other person to monopolize any part of trade or commerce."

281. As set forth in detail above, Amgen violated § 6-1-105 *et seq*. of the Colorado Revised Statute (as well as § 6-4-105) by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

282. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

283. The plaintiffs' and class members' injuries are of the type that § 6-1-105 *et seq.* was intended to prevent.

284. The plaintiffs are entitled to bring this action for damages pursuant to § 6-1-105, *et seq.* of the Colorado Revised Code.

285. The plaintiffs are entitled to recover their actual damages and injunctive relief, along with reasonable attorneys' fees and costs, pursuant to § 6-1-113 of the Colorado Revised Code.

4. D.C. Code §§ 28-3901, *et seq.* (with respect to the plaintiffs' and class members' purchases in the District of Columbia)

286. District of Columbia Code § 28-3904 provides that "[i]t shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice. . . ."

287. District of Columbia Code § 28-4502 provides that every contract or conspiracy "in restraint of trade or commerce all or any part of which is within the District of Columbia is declared to be illegal."

288. District of Columbia Code § 28-4503 provides that it shall be unlawful for any person "to monopolize, attempt to monopolize, or combine or conspire with any other person or persons to monopolize any part of trade or commerce, all or any part of which is within the District of Columbia."

289. As set forth in detail above, Amgen violated §§ 28-3901 *et seq.* of the District of Columbia Code by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

290. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

291. The plaintiffs' and class members' injuries are of the type that §§ 28-3901 *et seq*. of the District of Columbia Code was intended to prevent.

292. The plaintiffs are entitled to bring this action for damages pursuant to § 28-3905 of the District of Columbia Code.

293. The plaintiffs are entitled to recover their actual damages, treble damages, and punitive damages, along with reasonable attorneys' fees as expenses, pursuant to § 28-3905(k) of the District of Columbia Code.

5. Fla. Stat. §§ 501.201 *et seq.* (with respect to the plaintiffs' and class members' purchases in Florida)

294. Section 501.204(1) of the Florida Statutes declares unlawful "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce."

295. As set forth in detail above, Amgen violated §§ 501.201 *et seq*. of the Florida Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

296. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

297. The plaintiffs' and class members' injuries are of the type that §§ 501.201 *et seq.* of the Florida Statutes was intended to prevent.

298. The plaintiffs are entitled to bring this action for damages pursuant to § 501.211 of the Florida Statutes.

299. The plaintiffs are entitled to recover their actual damages, along with reasonable attorneys' fees and expenses, pursuant to §§ 501.211 & 501.2015 of the Florida Statutes.

6. 815 Ill. Comp. Stat. Ann. §§ 505/1 *et seq*. (with respect to the plaintiffs' and class members' purchases in Illinois)

300. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Illinois Compiled Statutes § 505/2, makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact . . . in the conduct of any trade or commerce."

301. As set forth in detail above, Amgen violated §§ 505/1 *et seq*. of the Illinois Compiled Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

302. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

303. The plaintiffs' and class members' injuries are of the type that §§ 505/1 *et seq*. of the Illinois Compiled Statutes was intended to prevent.

304. The plaintiffs are entitled to bring this action for damages pursuant to § 505/10a of the Illinois Compiled Statutes.

305. The plaintiffs are entitled to recover their actual damages and punitive damages, along with reasonable attorneys' fees and costs, pursuant to §§ 505/10a(a) & 505/10a(c) of the Illinois Compiled Statutes.

7. La. Rev. Stat. Ann. § 51:1401 *et seq*. (with respect to the plaintiffs' and class members' purchasers in Louisiana)

306. The Louisiana Unfair Trade Practices and Consumer Protection Law, §§ 51:1401 et seq. of the Louisiana Revised Statutes, declares unlawful "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

307. As set forth in detail above, Amgen violated the Louisiana Unfair Trade Practices and Consumer Protection Law by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

308. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

309. The plaintiffs' and class members' injuries are of the type that Louisiana Unfair Trade Practices and Consumer Protection Law was intended to prevent.

310. The plaintiffs are entitled to bring this action for damages pursuant to § 51:1409 of the Louisiana Revised Statutes.

8. 5 Md. Code, Com. Law §§ 13-301 et seq. (with respect to the plaintiffs' and class members' purchasers in Maryland)

311. Section 13-303 of the Maryland Code provides that "[a] person may not engage in any unfair, abusive, or deceptive trade practice, as defined in this subtitle or as further defined by the Division, in . . . [t]he sale, lease, rental, loan, or bailment of any consumer goods, consumer realty, or consumer services . . . .

312. As set forth in detail above, Amgen violated the §§ 13-301 et seq. of the Maryland Code by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—deceptive and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

313. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

314. The plaintiffs' and class members' injuries are of the type that §§ 13-301 et seq. of the Maryland Code was intended to prevent.

315. The plaintiffs are entitled to bring this action for damages pursuant to § 13-408 of the Maryland Code.

9. Mich. Comp. Laws Ann. §§ 445.901 *et seq*. (with respect to the plaintiffs' and class members' purchasers in Michigan)

316. Section 445.903 of the Michigan Compiled Laws provides that "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce are unlawful."

317. As set forth in detail above, Amgen violated §§ 445.901 *et seq*. of the Michigan Compiled Laws by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair, unconscionable, and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

318. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

319. The plaintiffs' and class members' injuries are of the type that §§ 445.901 *et seq*. of the Michigan Compiled Laws was intended to prevent.

320. The plaintiffs are entitled to bring this action for damages pursuant to § 445.911 of the Michigan Compiled Statutes.

321. The plaintiffs are entitled to recover their actual damages and punitive damages, along with reasonable attorneys' fees, pursuant to § 445.911 of the Michigan Compiled Statutes.

10. Minn. Stat. §§ 325F.68, *et seq*., with respect to the plaintiffs' and class members' purchases in Minnesota.

322. Section 325D.44 of the Minnesota Statutes provides that "[a] person engages in a deceptive trade practice when, in the course of business, vocation, or occupation, the person . . . engages in (i) unfair methods of competition, or (ii) unfair or unconscionable acts or practices."

323. Section 325F.69 of the Minnesota Statutes provides:

> The act, use, or employment by any person of any fraud, unfair or unconscionable practice, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoinable . . . .

324. As set forth in detail above, Amgen violated §§ 325D.43 *et seq.* of the Minnesota Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

325. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

326. The plaintiffs' and class members' injuries are of the type that §§ 325D.43 *et seq.* of the Minnesota Statutes was intended to prevent.

327. The plaintiffs are entitled to bring this action for damages pursuant to § 8.31 of the Minnesota Statutes

328. The plaintiffs are entitled to recover their actual damages, along with reasonable attorneys' fees and costs, pursuant to § 8.31 of the Minnesota Statutes.

11. Miss. Code Ann. §§ 75-24-5 et seq. (with respect to the plaintiffs' and class members' purchases in Mississippi)

329. Section 75-24-5 of the Mississippi Code prohibits "unfair methods of competition affecting commerce and unfair or deceptive trade practices in or affecting commerce."

330. As set forth in detail above, Amgen violated §§ 75-24-5 et seq. of the Mississippi Code by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay

and/or block competition—unfair and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

331. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

332. The plaintiffs' and class members' injuries are of the type that §§ 75-24-5 et seq. of the Mississippi Code was intended to prevent.

333. The plaintiffs are entitled to bring this action for damages pursuant to § 75-24-15 of the Mississippi Code

12. Mo. Rev. Stat. §§ 407.010 *et seq*. (with respect to the plaintiffs' and class members' purchases in Missouri)

334. Section 407.020 of the Missouri Statutes provides:

> [T]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose, as defined in section 407.453, in or from the state of Missouri, is declared to be an unlawful practice.

335. As set forth in detail above, Amgen violated §§ 407.010 *et seq*. of the Missouri Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

336. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

337. The plaintiffs' and class members' injuries are of the type that §§ 407.20 *et seq*. of the Missouri Statutes was intended to prevent.

338. The plaintiffs are entitled to bring this action for damages pursuant to § 407.025 of the Missouri Statutes.

13. Neb. Rev. Stat. §§ 59-1601 et seq. (with respect to the plaintiffs' and class members' purchases in Nebraska)

339. Nebraska's Consumer Protection Act, Nebraska Revised Statutes §§ 59-1602, provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce shall be unlawful."

340. Section 59-1603 of the Nebraska Revised Statutes provides that "any contract, combination, in the form of trust or otherwise, or conspiracy in restraint of trade or commerce shall be unlawful."

341. Section 59-1604 of the Nebraska Revised Statutes provides that "it shall be unlawful for any person to monopolize, or attempt to monopolize or combine or conspire with any other person or persons to monopolize any part of trade or commerce."

342. As set forth in detail above, Amgen violated §§ 59, 1602, 59-1603 & 59-1604 of the Nebraska Revised Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

343. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

344. The plaintiffs' and class members' injuries are of the type that §§ 59-1601 *et seq*. of the Nebraska Revised Statutes was intended to prevent.

345. The plaintiffs are entitled to bring this action for damages pursuant to § 59-1609 of the Nebraska Revised Statutes.

14. Nev. Rev. Stat. §§ 598.0903 *et seq*. (with respect to class members' purchases in Nevada)

346. Section 41.600 of the Nevada Revised Statutes provides that "an action may be brought by any person who is a victim of consumer fraud. "Consumer fraud" means "a deceptive trade practice as defined in NRS 598.0915 to 598.0925, inclusive.

347. Section 598.015 of the Nevada Revised Statutes provides:

> A person engages in a "deceptive trade practice" if, in the course of his or her business or occupation, he or she . . . [m]akes false or misleading statements of fact concerning the price of goods or services for sale or lease, or the reasons for, existence of or amounts of price reductions.

348. Section 598.0923 of the Nevada Revised Statutes provides that "[a] person engages in a 'deceptive trade practice' when in the course of his or her business or occupation he or she knowingly . . . uses an unconscionable practice in a transaction."

349. As set forth in detail above, Amgen violated §§ 598.0903 *et seq*. of the Nevada Revised Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

350. As a direct and proximate result of Amgen's conduct, class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

351. Class members' injuries are of the type that §§ 598.0903 *et seq*. of the Nevada Revised Statutes was intended to prevent.

352. The plaintiffs are entitled to bring this action for damages pursuant to § 41.600 of the Nevada Revised Statutes.

353. Class members are entitled to recover actual damages, along with costs and reasonable attorneys' fees, pursuant to § 41.600 of the Nevada Revised Statutes.

15. N.H. Rev. Stat. §§ 358-A:1 et seq. (with respect to the plaintiffs' and class members' purchases in New Hampshire)

354. Section 358-A:2 of the New Hampshire Revised Statutes provides:

> It shall be unlawful for any person to use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state. Such unfair method of competition or unfair or deceptive act or practice shall include, but is not limited to, the following:
>
> . . .
>
> XIV. Pricing of goods or services in a manner that tends to create or maintain a monopoly, or otherwise harm competition, including the pricing of generic prescription drugs.

355. As set forth in detail above, Amgen violated §§ 358-A:1 *et seq*. of the New Hampshire Revised Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

356. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

357. The plaintiffs' and class members' injuries are of the type that §§ 358-A:1 *et seq.* of the New Hampshire Revised Statutes was intended to prevent.

358. The plaintiffs are entitled to bring this action for damages pursuant to § 358-A:10 of the New Hampshire Revised Statutes.

359. Because Amgen's conduct constitutes a willful or knowing violation of § 358-A:2 of the New Hampshire Revised Statutes, the plaintiffs are entitled to recover a damages award up to three times the amount of their actual damages, along with the costs of suit and reasonable attorneys' fees, pursuant to § 358-A:10 of the New Hampshire Revised Statutes.

16. N.M. Stat. Ann. §§ 57-12-1 et seq. (with respect to the plaintiffs' and class members' purchases in New Mexico)

360. Section 57-12-3 of the New Mexico Statutes provides that "[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce are unlawful."

361. As set forth in detail above, Amgen violated §§ 57-12-1 *et seq.* of the New Mexico Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair, deceptive acts, and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

362. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

363. The plaintiffs' and class members' injuries are of the type that §§ 57-12-1 *et seq*. of the New Mexico Statutes was intended to prevent.

364. The plaintiffs are entitled to bring this action for damages pursuant to § 57-12-10 of the New Mexico Statutes.

365. Because Amgen's conduct constitutes a willful violation of § 57-12-10 of the New Mexico Statutes, the plaintiffs are entitled to recover a damages award up to three times the amount of their actual damages, along with the costs of suit and reasonable attorneys' fees, pursuant to § 57-12-10 of the New Mexico Statutes.

17. N. Y. Gen. Bus. Law §§ 349 et seq. (with respect to the plaintiffs' and class members' purchases in New York)

366. Section 349(a) of the New York General Business Law provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful.

367. As set forth in detail above, Amgen violated §§ 349 *et seq*. of the New York General Business Law by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair, deceptive acts, and unconscionable acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

368. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

369. The plaintiffs' and class members' injuries are of the type that §§ 349 *et seq*. of the New York General Business Law was intended to prevent.

370. The plaintiffs are entitled to bring this action for damages pursuant to § 349(h) of the New York General Business Law.

371. Because Amgen's conduct constitutes a willful or knowing violation of § 349(a) of the New York General Business Law, the plaintiffs are entitled to recover a damages award up to three times the amount of their actual damages up to one thousand dollars, along reasonable attorneys' fees, pursuant to § 349(h) of the New York General Business Law.

18. N.C. Gen. Stat. §§ 75-1.1 et seq. (with respect to the plaintiffs' and class members' purchases in North Carolina)

372. Section 75-1.1(a) of the North Carolina General Statutes provides that "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are declared unlawful."

373. As set forth in detail above, Amgen violated §§ 75-1.1 *et seq*. of the North Carolina General Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

374. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

375. The plaintiffs' and class members' injuries are of the type that §§ 75-1.1 *et seq*. of the North Carolina General Statutes was intended to prevent.

376. The plaintiffs are entitled to bring this action for damages pursuant to § 75-16 of the North Carolina General Statutes.

377. The plaintiffs are entitled to recover a damages award up to three times the amount of their actual damages pursuant to § 75-16.1 of the North Carolina General Statutes. Because Amgen's conduct constitutes a willful violation of § 75-1.1(a) of the North Carolina General Statutes, the plaintiffs are also entitled to recover costs of suit and reasonable attorneys' fees.

19. Or. Rev. Stat. §§ 646.605 et seq. (with respect to the plaintiffs' and class members' purchases in Oregon)

378. Section 646.608 of the Oregon Revised Statutes provides that "[a] person engages in an unlawful practice if in the course of the person's business, vocation or occupation the person . . . [e]ngages in any other unfair or deceptive conduct in trade or commerce."

379. As set forth in detail above, Amgen violated §§ 646.605 et seq. of the Oregon Revised Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

380. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

381. The plaintiffs' and class members' injuries are of the type that §§ 646.605 et seq. of the Oregon Revised Statutes was intended to prevent.

382. The plaintiffs are entitled to bring this action for damages pursuant to § 646.648 of the Oregon Revised Statutes.

383. The plaintiffs are entitled to their actual damages and punitive damages, along with reasonable attorneys' fees and costs, pursuant to § 646.638 of the Oregon Revised Statutes.

20. 73 Pa. Stat. Ann. §§ 201-1 et seq. (with respect to the plaintiffs' and class members' purchases in Pennsylvania)

384. Section 201-3 of the Pennsylvania Statutes declares unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

385. As set forth in detail above, Amgen violated §§ 201-1 et seq. of the Pennsylvania Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

386. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

387. The plaintiffs' and class members' injuries are of the type that §§ 201-1 et seq. of the Pennsylvania Statutes was intended to prevent.

388. The plaintiffs are entitled to bring this action for damages pursuant to § 201-9.2 of the Pennsylvania Statutes.

389. The plaintiffs are entitled to a damages award of up to three times the amount of their actual damages, along with reasonable attorneys' fees and costs, pursuant to § 201-9.2 of the Pennsylvania Statutes.

21. S.C. Stat. §§ 39-5-10 et seq. (with respect to the plaintiffs' and class members' purchases in South Carolina)

390. Section 39-50-20 of the Code of Laws of South Carolina provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

391. As set forth in detail above, Amgen violated §§ 39-50-10 et seq. of the Code of Laws of South Carolina by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

392. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

393. The plaintiffs' and class members' injuries are of the type that §§ 39-50-10 et seq. of the Code of Laws of South Carolina was intended to prevent.

394. The plaintiffs are entitled to bring this action for damages pursuant to § 39-5-140 of the Code of Laws of South Carolina.

395. Because Amgen's conduct constitutes a willful or knowing violation of § 39-5-20, the plaintiffs are entitled to a damages award of up to three times the amount of their actual damages, along with reasonable attorneys' fees, pursuant to § 39-5-140 of the Code of Laws of South Carolina.

22. S.D. Codified Laws §§ 37-24-1 et seq. (with respect to class members' purchases in South Dakota)

396. Section 37-24-6 of the South Dakota Codified Laws provides that "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

> It is a deceptive act or practice for any person to . . . [k]nowingly act, use, or employ any deceptive act or practice, fraud, false pretense, false promises, or misrepresentation or to conceal, suppress, or omit any material fact in connection with the sale or advertisement of any merchandise or the solicitation of contributions for charitable purposes, regardless of whether any person has in fact been misled, deceived, or damaged thereby . . . .

397. As set forth in detail above, Amgen violated §§ 37-24-1 et seq. of the South Dakota Codified Laws by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

398. As a direct and proximate result of Amgen's conduct, class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

399. Class members' injuries are of the type that §§ 37-24-1 et seq. of the South Dakota Codified Laws was intended to prevent.

400. The plaintiffs are entitled to bring this action for damages pursuant to § 37-24-31 of the South Dakota Codified Laws.

23. Utah Code Ann. §§ 13-11-1 et seq. (with respect to the plaintiffs' and class members' purchases in Utah)

401. Section 13-11-5 of the Utah Code provides that "[a]n unconscionable act or practice by a supplier in connection with a consumer transaction violates this act whether it occurs before, during, or after the transaction."

402. As set forth in detail above, Amgen violated §§ 13-11-1 et seq. of the Utah Code by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

403. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

404. The plaintiffs' and class members' injuries are of the type that §§ 13-11-1 et seq. of the Utah Code was intended to prevent.

405. The plaintiffs are entitled to bring this action for damages pursuant to § 13-1119 of the Utah Code.

406. The plaintiffs are entitled to recover their actual damages, along with reasonable attorneys' fees and court costs, pursuant to § 13-11-19 of the Utah Code.

24. Vt. Stat. Ann. tit. 9, §§ 2453 et seq. (with respect to the plaintiffs' and class members' purchases in Vermont)

407. Section 2453 of the Vermont Statutes provides that "[a]n unconscionable act or practice by a supplier in connection with a consumer transaction violates this act whether it occurs before, during, or after the transaction."

408. As set forth in detail above, Amgen violated §§ 2453 et seq. of the Vermont Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

409. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

410. The plaintiffs' and class members' injuries are of the type that §§ 2453 et seq. of the Vermont Statutes was intended to prevent.

411. The plaintiffs are entitled to bring this action for damages pursuant to § 2453 of the Vermont Statutes.

25. Va. Code Ann. §§ 59.1-196 et seq. (with respect to the plaintiffs' and class members' purchases in Virginia)

412. Section 59-1-200 of the Virginia Code provides:

> A. The following fraudulent acts or practices committed by a supplier in connection with a consumer transaction are hereby declared unlawful:
>
> . . .
>
> 14. Using any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction.

413. As set forth in detail above, Amgen violated §§ 59-1-196 et seq. of the Virginia Code by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

414. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

415. The plaintiffs' and class members' injuries are of the type that §§ 59-1-196 et seq. of the Virginia Code was intended to prevent.

416. The plaintiffs are entitled to bring this action for damages pursuant to § 59-1.204 of the Virginia Code.

417. Because Amgen's conduct was willful, the plaintiffs are entitled to a damages award of up to three times the amount of their actual damages, along with reasonable attorneys' fees and court costs, pursuant to § 59.1-204 of the Virginia Code.

26. W. Va. Code §§ 46A-6-101 et seq. (with respect to the plaintiffs' and class members' purchases in West Virginia)

418. Section 46A-6-104 of the West Virginia Code declares unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

419. As set forth in detail above, Amgen violated §§ 46A-6-101 et seq. of the West Virginia Code by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose,

and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

420. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

421. The plaintiffs' and class members' injuries are of the type that §§ 46A-6-101 et seq. of the West Virginia Code was intended to prevent.

422. The plaintiffs are entitled to bring this action for damages pursuant to § 46A-6-104 of the West Virginia Code

27. Wis. Stat. § 100.20, et. seq. (with respect to the plaintiffs' and class members' purchases in Wisconsin)

423. Section 100-20 of the Wisconsin Statutes prohibits "[u]nfair methods of competition in business and unfair trade practices in business."

424. As set forth in detail above, Amgen violated §§ 100.20 et seq. of the Wisconsin Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

425. As a direct and proximate result of Amgen's conduct, the plaintiffs and class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

426. The plaintiffs' and class members' injuries are of the type that §§ 100.20 et seq. of the Wisconsin Statutes was intended to prevent.

427. The plaintiffs are entitled to bring this action for damages pursuant to § 100.20 of the Wisconsin Statutes.

428. The plaintiffs are entitled to a damages award of twice the amount of their actual pecuniary loss, along with reasonable attorneys' fees and court costs, pursuant to § 100.20(5) of the Wisconsin Statutes.

28. Wyo. Stat. Ann. §§ 40-12-101 et seq. (with respect to the class members' purchases in Wyoming)

429. Section 40-12-105 of the Wyoming Statutes provides

> A person engages in a deceptive trade practice unlawful under this act when, in the course of his business and in connection with a consumer transaction, he knowingly . . . [e]ngages in unfair or deceptive acts or practices[.]

430. As set forth in detail above, Amgen violated §§ 40-12-101 et seq. of the Wyoming Statutes by wrongfully acquiring the rights to the Roche Patents and using them to unlawfully delay and/or block competition—unfair and deceptive acts that had the goal, purpose, and effect of delaying and/or blocking the launch of etanercept biosimilars, extending Amgen's monopoly in the etanercept market, and maintaining supracompetitive prices for Enbrel.

431. As a direct and proximate result of Amgen's conduct, class members suffered injury and actual damages in the form of paying higher prices for etanercept than they would have paid but for Amgen's conduct.

432. Class members' injuries are of the type that §§ 40-12-101 et seq. of the Wyoming Statutes was intended to prevent.

433. The plaintiffs are entitled to bring this action for damages pursuant to § 40-12-108 of the Wyoming Statutes.

COUNT FOUR

UNJUST ENRICHMENT UNDER STATE LAW

434. The plaintiffs repeat and incorporate the above paragraphs as though fully set forth herein.

435. To the extent required, this claim is pleaded in the alternative to the other claims in this complaint.

436. As a result of its unlawful conduct described above, Amgen has and will continue to be unjustly enriched by the receipt of unlawfully inflated prices and unlawful profits from sales of etanercept. Amgen's financial benefits are traceable to the plaintiffs' and class members' overpayments for etanercept. Amgen has received a benefit from the class in the form of revenue resulting from unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class. Amgen has benefited from its unlawful acts, and it would be inequitable for Amgen to retain any of the ill-gotten gains resulting from the plaintiffs' and class members' overpayments for etanercept during the class period.

437. It would be futile for the plaintiffs and class members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Enbrel, as those intermediaries are not liable for, and would not compensate the plaintiffs and class members for, Amgen's unlawful conduct.

438. The economic benefit Amgen derived from the plaintiffs' and class members' purchases of etanercept is a direct and proximate result of Amgen's unlawful and anticompetitive practices.

439. The financial benefits Amgen derived are ill-gotten gains that rightfully belong to the plaintiffs and class members who paid and continue to pay artificially inflated prices that inured to Amgen's benefit.

440. It would be inequitable under unjust enrichment principles under the laws of the jurisdictions identified below for Amgen to retain any of the benefits Amgen derived from its unfair, anticompetitive, and unlawful methods, acts, and trade practices.

441. Amgen is aware of and appreciates the benefits that the plaintiffs and class members have bestowed upon it.

442. Amgen should be ordered to disgorge all unlawful or inequitable proceeds it received to a common fund for the benefit of the plaintiffs and class members who collectively have no adequate remedy at law.

443. A constructive trust should be imposed upon all unlawful or inequitable sums Amgen received that are traceable to the plaintiffs and class members.

444. By engaging in the unlawful or inequitable conduct described above, which deprived the plaintiffs and class members of the opportunity to purchase lower-priced biosimilar versions of etanercept and forced them to pay higher prices for Enbrel, Amgen has been unjustly enriched in violation of the common law of the following jurisdictions:

1. Alabama

445. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Alabama. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

446. Amgen received money from the plaintiffs and class members as a direct result of the unlawful overcharges and has retained this money.

447. Amgen has benefitted at the expense of the plaintiffs and class members from revenue resulting from unlawful overcharges for etanercept.

448. It is inequitable for Amgen to accept and retain the benefits received without compensating the plaintiffs and class members.

2. Alaska

449. Amgen unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for etanercept in Alaska. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

450. Amgen has received a benefit from class members in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen, to the economic detriment of class members.

451. Amgen appreciated the benefits bestowed upon it by class members.

452. Amgen accepted and retained the benefits bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to class members.

453. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating class members.

3. Arizona

454. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Arizona. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

455. Amgen has been enriched by revenue resulting from unlawful overcharges for etanercept.

456. The plaintiffs and class members have been impoverished by the overcharges for etanercept resulting from Amgen's unlawful conduct.

457. Amgen's enrichment and the impoverishment of the plaintiffs and class members are connected. Amgen has paid no consideration to any other person for any benefits it received from the plaintiffs and class members.

458. There is no justification for Amgen's receipt of the benefits causing its enrichment and the impoverishment of the plaintiffs and class members because the plaintiffs and class members paid supracompetitive prices that inured to Amgen's benefit, and it would be inequitable for Amgen to retain any revenue gained from its unlawful overcharges.

459. The plaintiffs and class members have no adequate remedy at law.

4. Arkansas

460. Amgen unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for etanercept in Arkansas. Class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

461. Amgen received money from class members as a direct result of the unlawful overcharges and has retained this money.

462. Amgen has paid no consideration to any other person in exchange for this money.

463. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating class members.

5. California

464. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in California. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

465. Amgen received a benefit from the plaintiffs and the class as a direct result of Amgen's fraudulent and misleading conduct and the resulting unlawful overcharges to the class.

466. Amgen retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the plaintiffs and the class.

467. The plaintiffs and members of the class are entitled to restitution from Amgen.

6. Colorado

468. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Colorado. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen 's actions.

469. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

470. Amgen retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the plaintiffs and the class.

471. Under the circumstances, it would be inequitable and unjust for Amgen to retain such benefits without compensating the plaintiffs and class members.

7. Connecticut

472. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Connecticut. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

473. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

474. Amgen has paid no consideration to any other person in exchange for this benefit.

475. Amgen retained the benefits bestowed upon it under inequitable and unjust circumstances at the expense of the plaintiffs and class members.

476. Under the circumstances, it would be inequitable and unjust for Amgen to retain such benefits.

8. Delaware

477. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Delaware. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

478. Amgen has been enriched by revenue resulting from unlawful overcharges for branded etanercept.

479. The plaintiffs and the class have been impoverished by the overcharges for branded etanercept resulting from Amgen's unlawful conduct.

480. Amgen's enrichment and the impoverishment of the plaintiffs and the class are connected. Amgen has paid no consideration to any other person for any benefits they received from the plaintiffs and class members.

481. There is no justification for Amgen's receipt of the benefits causing its enrichment and the impoverishment of the plaintiffs and the class because the plaintiffs and the class paid supracompetitive prices that inured to Amgen's benefit, and it would be inequitable for Amgen to retain any revenue gained from its unlawful overcharges.

482. The plaintiffs and the class have no remedy at law.

9. District of Columbia

483. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in the District of Columba. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

484. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen, to the economic detriment of the plaintiffs and the class.

485. Amgen accepted and retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the class.

486. Under the circumstances, it would be inequitable and unjust for Amgen to retain such benefits.

10. Florida

487. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Florida. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

488. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

489. Amgen appreciated and retained the benefit bestowed upon it by the plaintiffs and class members.

490. It is inequitable and unjust for Amgen to accept and retain such benefits without compensating the plaintiffs and class members.

11. Georgia

491. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Georgia. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

492. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

493. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the plaintiffs and the class.

12. Hawaii

494. Amgen unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for etanercept in Hawaii. Class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

495. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of class members.

496. It is unjust for Amgen to retain such benefits without compensating class members.

13. Idaho

497. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Idaho. The plaintiffs and

class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

498. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

499. Amgen appreciated the benefit conferred upon it by the class.

500. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

14. Illinois

501. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Illinois. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

502. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

503. Amgen retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

504. It is against equity, justice, and good conscience for Amgen to be permitted to retain the revenue resulting from its unlawful overcharges without compensating the plaintiffs and class members.

15. Iowa

505. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Iowa. The plaintiffs and

class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

506. Amgen has been enriched by revenue resulting from unlawful overcharges for etanercept, which revenue resulted from anticompetitive prices paid by the class, which inured to Amgen's benefit.

507. Amgen's enrichment has occurred at the expense of the class.

508. It is against equity and good conscience for Amgen to retain such benefits without compensating the class.

16. Kansas

509. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Kansas. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

510. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

511. Amgen retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

512. Amgen was unjustly enriched at the expense of the plaintiffs and the class members.

17. Kentucky

513. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Kentucky. The plaintiffs

and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

514. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

515. Amgen appreciated the benefit bestowed upon it by the class.

516. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

18. Louisiana

517. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Louisiana. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

518. Amgen has been enriched by revenue resulting from unlawful overcharges for etanercept.

519. The plaintiffs and class members have been impoverished by the overcharges for etanercept resulting from Amgen's unlawful conduct.

520. Amgen's enrichment and the impoverishment of the plaintiffs and the class are connected.

521. There is no justification for Amgen's receipt of the benefits causing its enrichment and the class's impoverishment because the plaintiffs and the class paid supracompetitive prices that inured to Amgen's benefit, and it would be inequitable for Amgen to retain any revenue gained from its unlawful overcharges.

522. The plaintiffs and the class have no other remedy at law.

19. Maine

523. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Maine. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

524. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

525. Amgen was aware of or appreciated the benefit bestowed upon it by the plaintiffs and the class.

526. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

20. Maryland

527. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Maryland. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

528. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen, to the economic detriment of the plaintiffs and the class.

529. Amgen was aware of or appreciated the benefit bestowed upon it by the class.

530. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

21. Massachusetts

531. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Massachusetts. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

532. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

533. Amgen was aware of and/or appreciated the benefit conferred upon it by the class.

534. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class. Fairness and good conscience require Amgen not be permitted to retain the revenue resulting from its unlawful overcharges at the expense of the plaintiffs and class members.

22. Michigan

535. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Michigan. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

536. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen.

537. Amgen retained the benefits bestowed upon it under unjust circumstances arising from unlawful overcharges to the class.

538. Amgen was unjustly enriched at the expense of the plaintiffs and the class members.

23. Minnesota

539. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Minnesota. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

540. Amgen appreciated and knowingly accepted the benefits bestowed upon it by the plaintiffs and class members. Amgen has paid no consideration to any other person for any of the benefits they have received from the plaintiffs and class members.

541. It would be inequitable for Amgen to accept and retain such benefits without compensating the class.

24. Mississippi

542. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Mississippi. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

543. Amgen received money from the class as a direct result of the unlawful overcharges. Amgen retains the benefit of overcharges received on the sales of brand etanercept, which in equity and good conscience belong to the class on account of Amgen's anticompetitive conduct.

544. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

25. Missouri

545. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Missouri. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

546. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

547. Amgen appreciated the benefit bestowed upon it by the class.

548. Amgen accepted and retained the benefit bestowed upon it under inequitable and unjust circumstances arising from unlawful overcharges to the class.

26. Montana

549. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Montana. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

550. The plaintiffs and the class have conferred an economic benefit upon Amgen in the form of revenue resulting from unlawful overcharges to the economic detriment of the plaintiffs and the class.

551. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

27. Nebraska

552. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Nebraska. The plaintiffs

and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

553. Amgen received money from the class as a direct result of the unlawful overcharges and have retained this money. Amgen has paid no consideration to any other person in exchange for this money.

554. In justice and fairness, Amgen should disgorge such money and remit the overcharged payments back to the class.

28. Nevada

555. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Nevada. Class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

556. Class members have conferred an economic benefit upon Amgen in the form of revenue resulting from unlawful overcharges.

557. Amgen appreciated the benefits bestowed upon it by the class, for which it has paid no consideration to any other person.

558. Amgen has knowingly accepted and retained the benefits bestowed upon it by class members.

559. The circumstance under which Amgen has accepted and retained the benefits bestowed on it by class members are inequitable in that they result from Amgen's unlawful overcharges.

29. New Hampshire

560. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in New Hampshire. The

plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

561. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

562. Under the circumstances, it would be unconscionable for Amgen to retain such benefits.

30. New Jersey

563. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in New Jersey. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

564. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

565. The benefits conferred upon defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the plaintiffs and class members.

566. Amgen has paid no consideration to any other person for any of the unlawful benefits they received from the plaintiffs and class members with respect to Amgen's sales of brand etanercept.

567. Under the circumstances, it would be unjust for defendants to retain such benefits without compensating the plaintiffs and class members.

31. New Mexico

568. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in New Mexico. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

569. Amgen has knowingly benefitted at the expense of the class from revenue resulting from unlawful overcharges for etanercept.

570. To allow Amgen to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Amgen's benefit and because Amgen has paid no consideration to any other person for any of the benefits it received.

32. New York

571. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in New York. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

572. Amgen has been enriched by revenue resulting from unlawful overcharges for brand etanercept, which revenue resulted from anticompetitive prices paid by the class, which inured to Amgen's benefit.

573. Amgen's enrichment has occurred at the expense of the class.

574. It is against equity and good conscience for Amgen to be permitted to retain the revenue resulting from its unlawful overcharges.

33. North Carolina

575. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in North Carolina. The

plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

576. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

577. The class did not interfere with Amgen's affairs in any manner that conferred these benefits upon Amgen.

578. The benefits conferred upon Amgen were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from Amgen's actions in delaying entry of generic versions of etanercept to the market and preventing fulsome generic competition in the market for etanercept.

579. The benefits conferred on Amgen are measurable, in that the revenue Amgen has earned due to unlawful overcharges are ascertainable by review of sales records.

580. Amgen consciously accepted the benefits conferred upon it and continues to do so as of the date of this filing.

34. North Dakota

581. Amgen unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for etanercept in North Dakota. Class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

582. Amgen has been enriched by revenue resulting from unlawful overcharges paid by plaintiffs and members of the class.

583. The class has been impoverished by the overcharges for etanercept resulting from Amgen's unlawful conduct.

584. Amgen's enrichment and the class's impoverishment are connected. Amgen has paid no consideration to any other person for any benefits it received directly or indirectly from class members.

585. There is no justification for Amgen's receipt of the benefits causing its enrichment because the class paid supracompetitive prices that inured to Amgen's benefit, and it would be inequitable for Amgen to retain any revenue gained from its unlawful overcharges.

586. The class has no remedy at law.

35. Oklahoma

587. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Oklahoma. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

588. Amgen received money from the plaintiffs and class members as a direct result of the unlawful overcharges and have retained this money.

589. Amgen has paid no consideration to any other person in exchange for this money.

590. The plaintiffs and class members have no remedy at law.

591. It is against equity and good conscience for Amgen to be permitted to retain the revenue resulting from its unlawful overcharges.

36. Oregon

592. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Oregon. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

593. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

594. Amgen was aware of the benefit bestowed upon it by the class.

595. Under the circumstances, it would be unjust for Amgen to retain any of the overcharges derived from its unfair conduct without compensating the plaintiffs and the class.

37. Pennsylvania

596. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Pennsylvania. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

597. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

598. Amgen was aware of and/or appreciated the benefit bestowed upon it by the class.

599. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

38. Puerto Rico

600. Amgen unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for etanercept in Puerto Rico. Class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

601. Amgen has been enriched by revenue resulting from unlawful overcharges.

602. The class has been impoverished by the overcharges for etanercept resulting from Amgen's unlawful conduct.

603. Amgen's enrichment and the class's impoverishment are connected.

604. There is no justification for Amgen's receipt of the benefits causing its enrichment and the class's impoverishment because the class paid supracompetitive prices that inured to Amgen's benefit, and it would be inequitable for Amgen to retain any revenue gained from its unlawful overcharges.

605. The class has no remedy at law.

39. Rhode Island

606. Amgen unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for etanercept in Rhode Island. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

607. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the class.

608. Amgen was aware of and/or recognized the benefit bestowed upon it by the class.

609. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

40. South Carolina

610. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in South Carolina. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

611. The benefits conferred upon Amgen were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from unlawful overcharges to the class.

612. Amgen realized value from the benefit bestowed upon it by the class.

613. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

41. South Dakota

614. Amgen unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for etanercept in South Dakota. Class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

615. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the class.

616. Amgen was aware of the benefit bestowed upon it by the class.

617. Under the circumstances, it would be inequitable and unjust for Amgen to retain such benefits without reimbursing class members.

42. Tennessee

618. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Tennessee. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

619. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

620. Amgen was aware of or appreciated the benefit bestowed upon it by the class.

621. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

622. It would be futile for the class to seek a remedy from any party with whom they have privity of contract. Amgen has paid no consideration to any other person for any of the unlawful benefits they received indirectly from the class with respect to Amgen's sale of etanercept. It would be futile for the class to exhaust all remedies against the entities with which the class has privity of contract because the class did not purchase etanercept directly from any defendant.

43. Texas

623. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Texas. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

624. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen, to the economic detriment of the plaintiffs and class members.

625. Amgen was aware of and/or appreciated the benefit bestowed upon it by the plaintiffs and class members.

626. The circumstances under which Amgen has retained the benefits bestowed upon it by the plaintiffs and class members are inequitable in that they result from Amgen's unlawful conduct.

627. The plaintiffs and class members have no remedy at law.

44. Utah

628. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Utah. The plaintiffs and

class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

629. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

630. Amgen was aware of and/or appreciated the benefit bestowed upon it by the class.

631. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

45. Vermont

632. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Vermont. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

633. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

634. Amgen accepted the benefit bestowed upon it by the class.

635. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

46. Virginia

636. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Virginia. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

637. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

638. Amgen was aware of the benefit bestowed upon it.

639. Amgen should reasonably have expected to repay the class.

640. The benefits conferred upon Amgen were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from the Amgen's illegal and unfair actions to inflate the prices of etanercept.

641. Amgen has paid no consideration to any other person for any of the benefits it has received from the class.

47. Washington

642. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Washington. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

643. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

644. Amgen was aware of and/or appreciated the benefit bestowed upon it by the class.

645. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

48. West Virginia

646. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in West Virginia. The

plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

647. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

648. Amgen was aware of and/or appreciated the benefit bestowed upon it by the class.

649. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

49. Wisconsin

650. Amgen unlawfully profited from overcharges paid by the plaintiffs and class members who made purchases of or reimbursements for etanercept in Wisconsin. The plaintiffs and class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

651. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the plaintiffs and the class.

652. Amgen was aware of and/or appreciated the benefit bestowed upon it by the class.

653. Under the circumstances, it would be inequitable for Amgen to retain such benefits without compensating the class.

50. Wyoming

654. Amgen unlawfully profited from overcharges paid by class members who made purchases of or reimbursements for etanercept in Wyoming. Class members paid higher prices for etanercept than they would have paid but for Amgen's actions.

655. Amgen has received a benefit from the class in the form of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Amgen and to the economic detriment of the class.

656. Amgen accepted, used, and enjoyed the benefits bestowed upon it by the class under inequitable and unjust circumstances arising from unlawful overcharges to class members.

657. Under the circumstances, it would be inequitable for Amgen to retain such benefits.

DEMAND FOR RELIEF

WHEREFORE, the plaintiffs, on behalf of themselves and the class members, respectfully demand that this Court:

A. Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure; direct that reasonable notice of this action, as provided by Rule 23(c)(2), be provided to the class; and declare the plaintiffs as the class representatives;

B. Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy the ongoing anticompetitive effects of Amgen's unlawful monopolization in the market for etanercept in the United States;

C. Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy Amgen attempted monopolization in the market for etanercept in the United States;

D. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

E. Enter judgment against Amgen and in favor of the plaintiffs and the class;

F. Award the class damages (including double or treble damages, where appropriate) in an amount to be determined at trial, plus interest in accordance with law;

G. Award the plaintiffs and the class members their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Award such further and additional relief as is necessary to correct for the anticompetitive market effects Amgen's unlawful conduct caused and as the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Dated: August 6, 2024

Respectfully submitted,

/s/ William H. Monroe, Jr.

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